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Commercialisation with knowledge in the pharmaceutical industry

- using the license agreement as an instrument for knowledge transfer

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Summary

This essay treats the commercialisation of knowledge in the pharmaceutical industry, primarily the part of the industry that is involved in the development of pharmaceuticals. The basis is to see how the actors commercialise knowledge through agreements. Since the license agreement is the most important type of agreement for knowledge transfer in the pharmaceutical industry, we have chosen to study such agreements in order to get a picture of how the commercialisation is done. The main part of this essay is therefore based on existing license agreement to which we have had access.

In the pharmaceutical industry there are three main actors active in commercialisation. These are actors originating from the academia, research companies and large pharmaceutical companies. The two former ones mainly act as suppliers of new knowledge and technology to the pharmaceutical companies, while the latter is the actor that, besides development, handles marketing and sales of pharmaceutical products. The large pharmaceutical companies' dependence on actors originating from the academia and on research companies has increased along with a keener competitive environment in the industry. The need of new inventions and products results in a steadily growing commercialisation with knowledge.

The license agreement is an extremely flexible instrument, which the parties can adapt after their needs and purposes. Even if all license agreements have similarities, each agreement is specific. We have chosen to more closely study how certain specific issues, that we find important for the commercialisation, are regulated in the agreements to which we have had access. We therefore more closely examine the license construction, improvements, performance of research and development activities, regulatory filings and approvals, adverse events, early termination, information duty, performance clauses and the regulation of intellectual property. We have found it to be very important for each party to regularly get informed of the other party's activities that is related to the agreement. It is also very important for a party to be able to evaluate and control the performance of the other party. Such regulations are always valuable for the licensor, but also for the licensee when the parties perform development together.

Regardless of which parties that are negotiating for a license agreement and which purpose they intend to achieve with it, there is a number of situations and issues, which the parties should carefully consider before the final draft of the agreement is signed. We have in the end of this essay gathered examples of such situations and issues, which we consider important for the parties to have in mind when they are negotiating for a license agreement that shall regulate development and/or commercialisation of pharmaceuticals.

1. Introduction

The development of the pharmaceutical industry has continuously advanced since man has been able to develop and produce pharmaceuticals. The speed of the development has though increased significantly during the last decade. Biotechnology and information technology have contributed with new methods to develop pharmaceuticals and have brought with them new products. Other important changes for the industry have been the increased regulatory requirements and the fact that cost efficiency has been put more in focus than before.

The development and commercialisation of pharmaceuticals is based on knowledge. Knowledge as intellectual property can appear in different figures such as patents, copyright, trademark, design, know-how etc. The most important of these are for the pharmaceutical industry patents and know-how. All these figures are no material objects but immaterial which means that they are products of an abstract process of humans.

Knowledge is nowadays considered as an asset that can be transferred between actors and its value as merchandise has increased. Intellectual property, which can be said to be a legal objectification of knowledge, is getting more and more important in the international trading market. The value of knowledge is though often difficult to estimate.

The development and commercialisation of a new pharmaceutical product is characterised of high risk-takings and costs. The inventor can therefore seldom finance or handle the further development of a basic innovation. Then an actor with financial and/or technical capacity can take over the project if it is deemed to have potential to become a future successful pharmaceutical product. Another way for the innovator to be able to continue his development by his own is to get financial aid from venture capitalists or other actors. The innovator can also decide to perform development in cooperation with actors having the capacity that the innovator lacks. Cooperation and contacts between actors in the industry are hence very common when developing pharmaceuticals. In such relations knowledge is being transferred between the actors. This is where the license agreement plays an important role. The license agreement has become the most important instrument through which knowledge transfer can be realised.

2. Object and method

2.1 The object of the essay

This essay treats the commercialisation of knowledge in the pharmaceutical industry. The main object of this essay is to map how commercialisation of knowledge can be done in this industry by studying the different actors in the pharmaceutical industry and how they act. Our aim is to distinguish better solutions from worse within this commercialisation and also to distinguish which solutions that best fulfil the goals of different actors.

Different interests guide the actors to perform commercial activities and we examine the shifting interests of the different actors, depending on when during the process of developing a pharmaceutical product they act. We also study the tools used by these actors involved in the commercialisation when they perform these activities. Such tools can be agreements or intellectual property rights.

The commercialisation of knowledge is very important for the pharmaceutical industry. This

is because the whole business in developing pharmaceutical products is based on knowledge. All pharmaceutical products have their origin in an invention, which is often protected as intellectual property, normally as patents and know-how. Patents and know-how are objectifications of knowledge. To be able to commercialise knowledge it is necessary to objectify a knowledge mass. Protection by intellectual property is one way to objectify knowledge. Another is to define specific knowledge in agreements.

The pharmaceutical industry has many special features. One of them is its knowledge intensity. Another is the obvious and constant presence of the academia. Furthermore the size of the actors active in the industry is quite specific. There are a large number of small companies, but only a few big ones. These big companies are though real multinational giants. In-between these two types of companies it does exist middle-sized companies, but these are neither commonplace nor significant. The trend in the industry seems to be that the number of the small companies is increasing at the same time as the large companies are getting even larger. The importance of the middle-sized companies also seems to decrease.

Small research-intensive companies and researchers in the academia have more or less become knowledge suppliers for the larger pharmaceutical companies. The importance of these actors as a part of the innovation process of the large companies has increased. A large amount of knowledge is therefore transferred from small actors to large ones. It is thus interesting to examine how these small actors manage, how they can influence the transfer and to what extent they are present in the further development and commercialisation of their knowledge.

The pharmaceutical industry is extensive and it has many different kinds of products. It consists for example of pharmaceuticals, diagnostics, medicine technical equipment, articles of consumption and means of assistance for disabled persons.[1] We only deal with the sector of this industry that concerns the developing of pharmaceutical products, mainly drugs. We can therefore not say whether our presentation is relevant for the other parts of the industry. The development process of diagnostics is similar to that of pharmaceutical, but it less time demanding and therefore also less expensive. We do though believe that the sector of diagnostics and of pharmaceuticals mainly functions in the same way, since their prerequisites are similar. The other sectors of the industry do not handle products that are based on biotechnology, since these products are material and technical items. When we later on in this essay use the notion “pharmaceutical industry” or just “industry” we refer thus only to the part of the industry that is our object, that is pharmaceuticals.

The part of the industry, in which a pharmaceutical is discovered, developed and commercialised is extremely research intensive. A pharmaceutical product can be developed either in-house or through contacts with other actors in the business. This essay focuses on the external relationships in the pharmaceutical sector. Mostly these external relationships are based on agreements. These agreements represent a transfer of knowledge, of intellectual property, as a means to commercialise knowledge.

There are many reasons that make this industry interesting. One reason is because it is often not the same actor that develops the invention that finally commercialises the product. This is due to the high costs and to the large risks, which are connected with the development of pharmaceutical products. Furthermore it takes a long time to develop a pharmaceutical

[1] NUTEK, pp 33

product from idea to a finished commercial product, but if a product becomes successful the economical profits can be enormous. However the majority of the up-started development projects are discontinued before they ever become end products. Another reason that makes the pharmaceutical industry interesting is that even though intellectual property is legally regulated in almost every country in the world, the commerce with these immaterial assets are often unregulated in the judicial area. This means that the actors in this industry have a wide scope to create and govern their own reality in which they act.

This wide scope of freedom for the actors to act independently when commercialising their knowledge affects the agreements the actors enters into. These agreements are the main tool by which the actors perform commercialisation activities. In order to find out how the actors commercialise knowledge, we have chosen to base our study on agreements. Licensing is the most important way to commercialise knowledge in the pharmaceutical industry, therefore it is license agreements that we have examined and analysed.

2.2 Method

A study of commercialisation of knowledge in the pharmaceutical industry could have its basis in how the actors are allowed to or must act when performing commercialisation activities. We do though not have such basis for our study. Instead our study is founded on how the actors actually do and could perform commercialisation of knowledge. Our basis is license agreements and we have not used any legal national or international regulations or legal cases. The essay has consequently first of all an analytical perspective. There are descriptive parts as well, but these are not so conspicuous. Such parts are mostly found in the first two chapters and there they are wrapped up in our analytical approach.

License agreement is the main source for the essay. These agreements have been supplied by different Swedish companies and found on the Internet. As a total we had access to 15 agreements and 13 of these were license agreements. We have also had access to an agreement proposal of a nonexclusive license. This agreement proposal was sent to us from a licensor and it can be seen as an expression of how he would like the final agreement to look like. The companies supplying us with contracts are both small research and development (later referred to as R&D) intensive firms and large international companies. It was not easy to find relevant agreements on the Internet. Though a large number of license agreements can be found on the Internet, they usually do not relate to the pharmaceutical industry. The agreements we did find were collected from the web site “FindLaw”.[2]

Besides the license agreement, other sources contributing with information have been articles found on the Internet, literature and the answers to a questionnaire that we sent to persons with knowledge in the pharmaceutical business. The answers to the questionnaire have been useful in every part of the essay, while the articles and literature mainly have been used as sources in the first parts.

In order to find out how the companies within the pharmaceutical industry commercialise knowledge we have chosen to use license agreements as our main source. In these agreements we analyse certain clauses and regulations by which the commercialisation is created. The chosen clauses and regulations are the ones that we consider being the most interesting and the most characteristic for the commercialisation of knowledge. Examining how actors in the

[2] http://techdeals.biz.findlaw.com

industry perform and how they could perform commercialisation constitute the main part of the essay.

To facilitate our presentation, but also to increase the comprehension for the readers we have chosen to categorise the different actors involved in commercialisation activities in the industry into three groups. These three are researchers in the academia, research firms and pharmaceutical companies. In the notion “researchers in the academia” we include all types of actors originating from the academic sphere, such actors can be single researcher(s), research institutions, universities or alike. Even though we usually only refer to researcher the other actors are comprised as well. With the notion “research firms” we mean small, at least in comparison with the large pharmaceutical companies, research-intensive firms. They can though be of very different characteristics and size. Our categorisation in three groups of actors is representative and accepted. It is also the categorisation that we find the most suitable for the purpose of this essay. Other categorisations may though be done.

Since commercial activities can be done during different stages of the development process of a pharmaceutical product, the life cycle of such a product is a relevant element in every part of the essay. We therefore begin with a description of this life cycle. Along with the description of the life cycle the different actors involved at different stages of the developing process are to be presented as well as their interests and goals. We also treat specific commercialisation activities the parties perform during the different phases of the life cycle of a pharmaceutical.

The essay then continues with the objectification of knowledge and different types of knowledge strategies the actors can use. A presentation of how knowledge is objectified by the different actors when they perform commercialisation then follows. The relevant agreements and the relevant intellectual property rights for the actors are examined. Thereafter the analysis of the gathered license agreements follows, which is the essence of the essay. The purpose of the analyse is to study how the actors through the selected agreements have regulated the commercialisation of knowledge. A prolongation of the purpose is to evaluate the different ways in which the commercialisation has been done in the agreements, by studying different clauses that specifically affect the commercialisation activity. This evaluation leads up to a short list, where different issues are to be presented that are important to have in mind while commercialising with knowledge within the pharmaceutical sector. Better solutions found in the agreements are to be distinguished from worse.

The number of the examined agreements is far too limited to give a representative picture of commercialisation through license agreements in the pharmaceutical industry. This is neither the aim of our presentation. The study of the agreements and of the relevant clauses can therefore not be seen as any statistic material. It is however an attempt to understand and explain how commercialisation with knowledge is being done as well as how it can be done in the chosen industry. As a basis for the analysis we perform we consider the number of the gathered agreements to be well sufficient.

In the essay we quote the studied agreements at several occasions. In all cases we have chosen to replace the names of the parties and instead we call them “Licensor” and “Licensee”. This is done even if we know the names of parties, in order to get the presentation more neutral. When words in the quotations begin with capital letters this means that a definition of these words or notions is found in the beginning of the agreement where all definitions are gathered. If we consider that an explanation of the definition of the word or notion has to be

shown this is done in brackets or in a footnote. Even if the agreement we quote is not a confidential one, we expose neither which agreement it is nor the parties. This is because some agreements are confidential and we therefore consider it to be most appropriate to treat all agreements in the same way.

3. The process from discovery to market introduction and its actors

3.1 Overview of the field and its features

Commercialisation of knowledge within the pharmaceutical industry is the main object of this essay. This commercialisation can find its expression in a transaction between two parties, where one sells or licenses his knowledge to the other. The commercialised knowledge in this industry is primarily patents and know-how. A pharmaceutical product can be seen as the result of a development process, an objectification and packaging of a certain knowledge mass consisting of patents and know-how. This whole procedure is necessary before any commercialisation can be done.

There is a close connection between the life cycle of a pharmaceutical product and the commercialisation of such a product. This life cycle stretches over a long period and contains different stages. At any time during these stages the commercialisation can be done. The commercialisation can hence have different expressions and comprehend different parties, with different interests and goals, depending on when it is performed.

The process of drug invention and development is lengthy, risky and expensive. For this reason there are often many actors involved in developing a new product and it is becoming increasingly rare that an actor totally in-house, without having any contact with others, develops a drug. To cooperate in the development process is a means to spread the risks and the costs, but it can have negative aspects as well. An example of such a negative aspect can be that the eventual future income becomes lesser.

Another reason why there are often many actors involved is the need of highly qualified collaborators and competence, which an actor active in any phase of the process may have a lack of. Some companies can have as their strategy to always outsource certain specific parts of the process of developing and commercialising pharmaceutical products, while others may have as their main strategy to handle the whole process, in which they are active, by themselves. These latter companies may though outsource activities when they have a lack of resources or are in need of competence.

Despite a wide-range of external contacts, there is always one party, a company or one or several person(s), that is the owner of the invention or the product. This owner may choose to let other actors perform parts of the development on a contractual basis, enter into joint development arrangements, grant a license or sell his rights. The actors engaged in the process differ during the different stages in the life cycle of a drug, depending on interests and competences, as well as their respective contributions.

The process to develop a drug takes about 10-15 years and the expenditures may exceed two thousand millions Swedish crowns.[3] During the last decades the research costs have heavily increased, especially the costs for clinical trials due to heightened regulatory demands on

[3] LIF, 1999, p 6

these trials.[4] Since developing drugs is expensive, it is necessary to develop such drugs that can be sold at high volumes and that can obtain large market shares.[5] During the development-period there are a great number of projects which are discontinued and a very few of the up-started projects will reach as far as the marketing of a new drug.[6] For such reasons it is important to continue with a project that seems to have a potential but also to discontinue as soon as possible with a project that does not meet the adequate requirements. Both when development is being made in collaboration with others and when the development work is being made without such collaboration it is therefore necessary to decide whether a project has a potential or not.

In order to continue only with the projects that seem to have a potential becoming a competitive product it is vital to continuously evaluate each project. The normal way for large pharmaceutical companies to control the projects in the development process appears to be through checkpoints or tollgates, at which the project is being examined. These checkpoints occur at some natural events in the development process and for each checkpoint there are well-defined standards, which the project must meet up to at each of these checkpoints. The standards can be based on scientific, economical or market requirements. For example the project can have an expenditure limit for each checkpoint that it must not exceed.

Even small companies in the pharmaceutical industry continuously control and evaluate their projects. As a consequence of their size they can though take more individual consideration to each project without being obliged to follow strict standards, as the larger ones often must do. For the smaller companies this can be an advantage, but for the larger ones a more strict control and evaluation system is necessary in order to maintain a cost-effective and competitive business.

The requirements of the high demands on clinical trials and on the numerous governmental approvals can be seen as something positive. Hopefully they decrease the number of products with unwanted and adverse effects in the market. Strict control should result in high standards on the launched products. However these circumstances do also have less positive sides. Perhaps several projects are discontinued too early due to their uncertain status and are thus not further developed even if they actually do have good potential becoming a competitive product. The high costs may result in knowledge loss, which can be difficult to repair. To focus too much on a certain project can also result in negligence of a substance that could be of importance for some other project. Pharmaceuticals are developed to cure certain diseases on humans but it is the industry that decides which diseases to focus on. In fact pharmaceuticals are today developed for diseases on which the actor can earn money. Their choice is thus not based on humanity but on economic matters. This is though something quite natural in a market economy.

The following presentation will describe the life cycle, the actors involved in this life cycle and their interests. The life cycle with its varied stages will form the basis of this presentation. Two words that will occur frequently are invention and innovation. The former is usually regarded as a technical idea eventually patentable and the latter is seen as a functional technology.[7] The difference between these words is though not completely clear and they are

[4] Domeij, p 7; NUTEK p 87
[5] NUTEK, p 83
[6] LIF, 1998, p 22
[7] Sandgren, 1995, p 24

often used as synonyms. We will therefore in the following presentation neither distinguish these two.

3.2 Pre-market

3.2.1 Pre-clinical phase

3.2.1.1 Elements of the phase

In general an identification of two main stages, pre-market and post-market, can be done. In these two there are several other stages. The pre-market stage consists of the pre-clinical and the clinical phase. The life of a new pharmaceutical begins with the discovery process. This process starts with a verbal identification of a medical need or a market. This identification is a prerequisite to develop a new pharmaceutical product. In the pre-clinical phase basic and applied research are used by medical, chemical and biological competences working close together to find a candidate drug. The pre-clinical phase is theoretic in its initial stage, but due to the complexity of the biological system theoretical studies are not sufficient and they have to be put into practice. This is done by performing practical tests.

Different methods, for example animal models and screening-methods, are used to find one or more substances most likely to be able to cure the relevant disease and have a possibility to compete with existing drugs. Pharmacological and toxicological studies are performed on animals, *in vivo*, and in tissue, *in vitro*, to study medical effects respective dangerous after-effects and risks. Hence in the pre-clinical phase only tests on animals and in test tubes are being used and it does not comprise tests on humans.[8]

3.2.1.2 Different actors involved and their interests

The pre-clinical phase is the very beginning of the discovery and the development of pharmaceutical products. The main actors involved in this first phase are researchers within the academia, research companies and pharmaceutical companies. In general it can be said that an invention often has its origin in the academia. Actually it is commonplace that big pharmaceutical companies have quite restricted basic research activities. They prefer to buy or license in projects when they have reached the stage when a patent can be filed. It is therefore vital for both research and pharmaceutical companies active in drug development to establish collaboration with universities and research institutes.[9]

The researchers within the academia are as a rule not market driven and commercialisation of their findings is not their primary aim. Instead it the usefulness of their research that is the most important for them. They are either actively researching to find a medicine for a certain disease or may discover an unexpected interesting quality of a substance while performing basic research or performing research for other determined projects. The researchers can be regarded as “idea injections” and thus a very important part of the development process.

In Sweden the academic researchers always obtain full ownership in the inventions they may develop. It is a law that gives them this ownership right.[10] This law is though optional. The researcher may therefore enter into agreements, which modify this principal rule stated by

[8] Eliasson, p 150; Bergenheim, pp 15; LIF, 1999; pp 6; Cardell, pp 49; Domeij, p 16
[9] NUTEK, p 49
[10] SFS 1949:345

law. Such an agreement may stipulate that the academic employer becomes the owner. Abroad it is as a rule the employing university that receives the ownership of the invention developed by the researcher. Especially in the US, the universities are good at commercialising the inventions developed by their researchers. The developing researcher then usually receives a percentage of the income earned by the university.[11]

In Sweden the universities and the researchers within the academia have been poor at commercialising with their developed innovations. The researchers often published their research results before applying for a patent and this made it difficult to obtain patent protection. During the last ten years the researchers and the universities have become aware of this problem and are more interested in commercialising with their inventions and knowledge.[12] Recently there have been companies established by the academia and the private sector in collaboration with the purpose to take better care of the innovative work within the academia. It is a good thing that the academia makes a display of its work and takes better care of its interests. Such establishments absorb important research discoveries and results to be further commercialised.

It is a matter of course that an invention also can have its origin in a company. The largest pharmaceutical companies are the source to almost every new pharmaceutical and also the driving force. All large multinational pharmaceutical companies basically have their own basic research departments, which supply them with new knowledge to be further developed. The internal R&D management within these large companies often requires that a certain number of projects are up-started each year. Often every department within a company must have a certain number of projects active in their department and these projects ought to pass through the department at certain intervals. Although a company has internal research department, all up-started and active projects do not as a rule have their source therefrom. Normally a certain part comes from external resources.

The external sources supplying companies with inventions are other companies or the academia. Companies that are supplying others with inventions are often small and research intensive. Such a company can be a so-called “start-up”. These are commonly established by researchers within the academia. The researcher can choose either to work exclusively in this start-up or to have it as a side project. If an invention with expected potentials is not developed further within a start-up, it is sold or licensed to an actor that has a commercial interest in the invention.

The reason why researchers choose to develop their inventions within companies owned by them is the possibility to earn more money when the invention finally is sold or licensed to an actor interested in commercialising it. The further an invention is developed the more valuable it gets as the certainty of its potential and its quality increases. It might as well be more inspiring for the researcher to perform research in a private-owned company in which he has a share or owns totally. A researcher having his origin in the academia has often a lot of contacts he can cooperate with and advantage from. He can make use of his invention by commercialise it to a much wider extent than within the academia.

Small research companies, which also usually have their origin in the academia, are often called “drug discovery firms”. They are as a rule only active in the pre-clinical phase and then they license patents and knowledge to big pharmaceutical companies. The research of these

[11] Koktvedgaard, pp 232
[12] NUTEK, p 103

firms is competence driven and not market driven, as is the research in the large ones.[13]

There are many firms that are specialised to function as an intermediate between the academia and the pharmaceutical industry. These firms often act as the party that discovers the potential of an innovation (e.g. the qualifications of a substance) developed in the academic sphere. Since they take over the development of the invention in an early stage, the price for it is low due to the uncertainty regarding the results of future development. Their interest is to use the innovation and develop it further for the purpose to become a pharmaceutical that the company can earn money on. When and if the project is successful the firm usually sells their developed innovation or gives a license to a big pharmaceutical company, hopefully with a large remuneration for the intermediary.[14] The intermediary firm can choose to sell or license the innovation late during the pre-clinical phase or during subsequent phases of the life cycle. At these stages a considerable increase in value of the developed invention has occurred.

One example of such a Swedish intermediary firm is A+Science Invest AB, which is located in Gothenburg. Their aim is to acquire and develop patentable innovations in medicine and biotechnology originating from the University of Gothenburg and other universities and research centres. The company assesses the patentability of the innovations and their market potential. Although A+ obtains exclusive ownership rights to all innovations, the inventing researchers are offered ownership in A+. The company strives to give their innovations a global patent protection and maximise their value. They then license or sell the projects to leading international pharmaceutical actors.[15]

Another example of an intermediary firm, which business, in contrary to A+'s, is not profit driven, is Karolinska Innovations AB, located in Stockholm. Their purpose is to support researchers and entrepreneurs at Karolinska Institutet and other universities in commercialising their intellectual property. They acquire the rights of the invention and then either out-license it directly to a pharmaceutical and/or biotechnology company, or create a company that will develop the invention further. The profits obtained through commercialisation of inventions are shared between Karolinska Innovations AB and the respective researchers. The company's own profit is then reinvested in commercialising new inventions.[16]

Companies, such as the two above mentioned, must be seen as a positive feature for the pharmaceutical industry. They facilitate the commercialisation of innovations developed in the academia. They make it possible for the researchers to concentrate on their innovative work, meanwhile these companies take care of the further steps in the commercialisation process. The fact that they handle the extensive administration connected with the innovation and its development is especially relieving for the researchers.

The start-ups, the drug discovery firms and the intermediary firms are often specialised in very restricted areas where they have specific knowledge and a core competence. Thanks to their small size they can be more flexible and cost-effective than the large pharmaceutical companies. These small firms seldom have the resources to handle the whole development of a pharmaceutical until market introduction, but they are often very innovative and are good at finding new pioneering technology.

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[13] NUTEK, p 91
[14] Nilsson, pp 11
[15] www.a-plusscience.se, 2001-01-19
[16] www.ki.se/innovations, 2001-01-19

To license or sell their technology to larger pharmaceutical companies is often the only way for these small firms to get money for their R&D projects and it is often necessary as well if they want their findings to become a successful drug. This is due to their lack of resources, market knowledge and competence in the later stages of the development of a pharmaceutical product. For these firms it is often more economically advantageous to license or sell their research results even though they will not get full economic profit of their technology if the drug becomes successful. The advantage is that they avoid a lot of risk taking.[17]

These small research companies tend to get increasingly important in the innovation process and the large companies are beginning to use these companies to a greater extent as their source that generates new products.[18] It is even usual that research projects that have been discontinued by large companies are taken over by small research companies, which then will proceed with the research the large ones have started. If the research then turns out to be successful the large companies might have an interest in licensing the results.

Big pharmaceutical companies always have an interest in new knowledge to be able to maintain a high commercialisation capacity and a competitive position in the market. The most important means of competition for researching companies is new and better products. For this reason it is common that such companies sponsor academic research. In return of financial support the big pharmaceutical companies receive access to and/or ownership in research findings and technology. The direction of this type of sponsored research is normally not determined by the sponsoring company. The sponsored researcher can hence perform and direct his activities freely without involvement from the financier.[19]

In the pre-clinical phase research cooperation is very common. This cooperation is mostly occurring between companies and institutes and the academia and consists mainly in exchange of knowledge, which is regulated in a cooperation agreement. Other ways for pharmaceutical companies to obtain new ideas are to sponsor research in the academia or to consult a person from the academia. The interest in consulting a researcher from the academia is to get access to his knowledge, ideas and experiences. The researcher is remunerated in exchange of his collaboration. It is not so frequent to collaborate between companies at this stage. This is due to the fact that it at this stage is difficult to determinate how to share the intellectual property rights that might arise from the cooperation. It is difficult at an early stage to know how the results of the collaboration will turn out and it is also difficult to know in advance which party that contributes with the breakthrough ideas and knowledge.

Parts of the pre-clinical development process that often are being outsourced by companies are receptor tests, toxicological tests and tests on animal models. The common motive for outsourcing a certain activity is to get access to competence, technology and resources that the company does not possess itself. Also economical factors, reputation, quality and trust influence the decision, as well as the commissioner's ability to perform results. There are specialised firms and laboratories that perform pre-clinical tests on a contractual basis. The relation between the parties is regulated in commissioned agreements. Tests that involve animals are often expensive and require large investments. Therefore it can be economically advantageous to outsource such tests. Some companies though prefer to handle these tests by themselves in order to maintain full control of the test activities and the results.

[17] Nilsson, p 8; Stankiewicz, pp 126
[18] NUTEK, p 82, 92
[19] Nilsson, p 8

3.2.1.3 Networks and informal contacts

It is not only contractual collaborations that are frequent and important during the pre-clinical phase. The informal contacts must not be underestimated and it is important to have a network of persons, who possess different types of competences, to collaborate with on both a formal (for example contractual) and an informal basis. The characteristics of these networks are that the persons in them possess different competences and knowledge and act in different market sectors. They complement and benefit from each other. In the networks competence is found to be more important than geographical closeness and collaboration over the boarders is rather the practice than an exception. Geographical closeness is though also important and this is why new research firms as a rule establish their business in close connection with the academia and other research companies, rather that in connection with large pharmaceutical companies.[20]

The informal contacts often have an individual character. They mostly occur in between scientists and researchers and it is not certain that the company employing these persons has any knowledge of such contacts. However this does not mean that the company is against informal contacts, because these can contribute to information that can be of interest for the company and that may come to their benefit. Many companies tend to give their researchers and scientists a large scope of freedom within which they can work independently. This is an instrument to create an innovative environment, so the researchers and scientists are inspired in their development work.

It is interesting how the increasing importance of knowledge as merchandise has resulted in a larger extent of deliberate formal and informal cooperation in the pharmaceutical industry. The hierarchy structure has been replaced by the flat network structure. For the pharmaceutical industry, which has huge development expenses, this change has been positive. Now it is possible for companies to only focus on their core competence and become specialists in a restricted area. Researchers and R&D intensive firms have become invaluable for the development of a new successful drug. Instead of neglecting and counteract competitors and other actors in the same market the actors are now more aware of the benefits that comes along with cooperation. Every actor is a needed link and the fact that researchers and R&D firms are regarded as important such links motivate them. The more credit they get the more inspired and willing to do innovative research they will be. As such the networks seem to be an environment where the interests of all the involved actors are observed and where they all can feel important and appreciated. It is thus no longer the big pharmaceutical companies that completely rule the roost.

3.2.1.4 Early patent and production aspects

As soon as a suitable substance has been identified an application for a patent is being filed. The owner of the substance, being one or several researcher(s), a company or a research institute, files this application. Often the patent application is being made during the first year of the development of a new active compound.[21] Due to the long administration process at the Patent and Registration Office[22], it is important to file the application in the earliest stage

[20] Nilsson, p 14; Domeij, p 7; Bergenheim, p 31
[21] LIF, 1998, p 8
[22] The Patent and Registration Office is the Swedish authority that handles patents. The situation with long administration period is similar in other countries.

possible. Since it is too insecure to invest in the development of a new drug before the scope of protection of the active compound is established, it is not until a patent has been granted that the real development starts.[23] The consequence is though that before a patent has been granted or at least an application has been filed it is difficult to attract investors to a project.

When the suitable substance has been found and the patent application has been filed the production of a product based on the substance starts. It is important to start with a test production as soon as possible in order to find out the most appropriate and profitable manufacturing method. It is also essential to decide which application forms that are the most suitable for the product and to test different application forms during the development process.[24]

3.2.2 Clinical phase

3.2.2.1 Elements of the phase

If the pre-clinical trials show that the substance has a therapeutically and economic value the project will enter into the clinical phase. An entrance into the clinical phase requires an exact opinion of the kind of product that shall be developed. In this phase the substance is tested on humans and the trials are made in clinics where there is access to patients. There are a lot of legal regulations regarding the tests in this phase and the governmental control has increased significantly during the last decades. The companies execute running quality controls of all clinical trials. These are not done only in order to meet the governmental demands, but also to have a good documentation over each project. It is then easier to discover any eventual shortages of a compound and the company has better possibilities to meet charges from different accusers.[25]

To test the substance on humans an official approval is required in the countries where the trials are going to take place.[26] An IND (Investigational New Drug[27]) application has therefore to be done. The official authority makes its decision, whether to give its approval or not, based on the documentation of the pre-clinical phase. Before the clinical trials start it can have passed five years since the project of developing a new drug started, including the time required for the authority to approve the IND.[28]

Within the clinical phase there are three different phases. In the first phase the substance is tested on a small group, normally 50-100 persons[29], of healthy individuals. Different doses, starting with small and then gradually increasing them, are given to the test persons in order to study the tolerance of the drug and to document how the body takes care of and eliminates

[23] LIF, 1998, p 8
[24] LIF, 1998, pp 22
[25] Domeij, p 6, 16; LIF, 1998, p 25
[26] The official authority in Sweden is the Medical Products Agency (MPA, Läkemedelsverket). The legal regulations that govern clinical trials in Sweden are the Medicinal Products Act, the Decree on Medicinal Products (SFS 1992:1752) and the regulation and general recommendations on clinical trials issued by MPA (LVFS 1996:17). There is also an umbrella agreement concerning clinical trials entered into by the Swedish Association of the Pharmaceutical industry (LIF) and the Swedish Federation of Country Councils (Landstingsförbundet).
[27] IND is what the application is called in the USA, but the term is used to describe this type of application in other countries as well.
[28] LIF, 1998, p 25
[29] www.neopharma.se, 2000-11-01

the substance. The first clinical phase generally takes one year to perform.[30]

In the second phase tests are performed on patients with the actual disease to evaluate if the substance has effect on the disease and to study the relation between dose, effect and tolerance. Trials are being made to establish the most effective dose. The group of patients in this phase are 50-300 and these studies proceed about two years. In the third phase the substance is tested on a larger group of humans to investigate if the results from the trials done so far are true when tested on a more varied group of patients during a long-time treatment. The effect of the drug in combination with other drugs on the market is also tested. In this phase the profile of the drug is finally established, the dose, the preparation-form and the circumstances to and not to prescribe the drug are being determined. This third phase is often the most expensive phase in the clinical trials and in general it also takes more time than the other to perform.[31]

As a total the clinical trials normally takes three to five years to execute.[32] The clinical trials, which consist of the three phases, commented above, are the most expensive part of the development of a new drug. About 30 per cent of the total cost for the development is related to these three phases. Normally nine of ten substances tested in clinical trials are found insufficient and are not further developed.[33]

3.2.2.2 Different actors and their interests

The main actors within the clinical phases are both small and large pharmaceutical companies and clinical test firms. The role of the academia is mainly as a performer of trials. In this phase there are more cooperation possibilities and this collaboration increases between competitors. This is due to the high costs connected with clinical trials and the need of leading-edge knowledge.

A pharmaceutical company can be either integrated or intermediary. The feature of an intermediary firm is, as discussed above under the pre-clinical phase, that it acts as a link between the academia and the large pharmaceutical companies. A firm that takes a product all the way to market introduction is regarded as an integrated firm. The large multinational companies are as a rule integrated, but an integrated firm can also, just as the intermediary firms, be small-sized. Though these integrated firms are fully responsible for the whole development process they may outsource some parts of the development process to other actors.

Although intermediary firms mainly are active in the pre-clinical phase they can also occur in the clinical phases, though they normally do not perform trials in phase three. To maintain their specialisation but also due to the large costs involved with clinical trials these firms prefer to transmit projects to larger companies instead of becoming an actor which takes the project to the market introduction. Business analysts consider it to be optimal if a research company licenses its project to a pharmaceutical company after clinical trials in phase one has been completed. To continue with clinical trials in the subsequent phases and not until then license the project is not regarded as economically advantageous, since the pharmaceutical

[30] Eliasson, p 150; Bergenheim, p 17; LIF, 1999; pp 9; Cardell, pp 49
[31] Eliasson, pp 150; Bergenheim, p 17; LIF, 1999; p 10; Cardell, pp 49
[32] LIF, 1998, p 25
[33] LIF, 1998, p 24, 26

companies do not pay much more for such further developed project.[34]

There is a tendency in the pharmaceutical industry towards concentration on the core competence the company possesses, in order to make business more economically effective. For that reason companies delimit their own activity to certain stages in the development of a pharmaceutical product, in which they are specialised and better than others, and outsource other activities to external suppliers.[35] In general it can be said that having an own over all covering organisation is very expensive and resource demanding.[36]

This tendency towards core competence, concentration and outsourcing should result in an establishment of several new companies with very specific knowledge in a medical area. This should to some extent contribute to highly specialised technologies and knowledge, which could generate new better pharmaceutical products. Persons active in development are given the opportunity to focus on a specific sphere and further develop their skill and competence. In the long run it should be regarded more positive to have a number of very specialised actors in different areas that can cooperate than a few "overall-covering" ones. This contributes to a healthier competition climate, which might lead to better research results. A risk is though that research areas in which there are no money to earn will be neglected. This can be negative for the industry in the long run, since it may fail to observe innovations that could be commercially successful. It may also be a disadvantage for humanity and the advance of research as such.

A few of the largest pharmaceutical companies are beginning to focus on clinical development and marketing and they let other actors concentrate on the discovery process. Larger firms buy or license in interesting projects from smaller, more research intensive ones. It can be more economic for a company to license in than develop competitive products in-house and it can be more efficient for the company to buy technique expertise or marketing prestige than to generate it internally.[37] In comparison to the large pharmaceutical companies, which in general are market driven, the intermediary firms are competence or technology driven.[38] Though this tendency of concentration most large pharmaceutical companies still handle the whole development process.

There are a just few real large pharmaceutical companies in the world, all of these are multinational. One such firm is GlaxoSmithKline (GSK), which was created in 2000 through the merger of Glaxo Wellcome and SmithKline Beecham. To merger companies is a tendency in the industry and it has become very frequent among large companies. The large companies tend to become even larger. GSK supplies products to 139 markets around the world and it perform R&D in seven countries. Their share in the world's pharmaceutical market is estimated to seven per cent. They are as the other large pharmaceutical companies very dependent on few products. 15 products represent over 60 per cent of their total pharmaceutical sales.[39]

The strive for cheaper and shorter drug development leads the pharmaceutical companies to outsource clinical trials. This outsourcing of clinical trials is done on a contractual research

[34] NUTEK, p 113
[35] NUTEK, p 48, 90
[36] Nordén, Licens- och Distributionsavtal
[37] Hodkinson, p 202
[38] NUTEK, p 91
[39] corp.gsk.com, 2001-02-22

basis. The main interest in outsourcing is to achieve more cost effective trials, which are made rapidly, with high quality and competence. This can also be seen as an element of the tendency among the pharmaceutical companies towards concentration on core competence. The focus of these companies specialised in clinical trials varies. It may be to investigate toxicity and acceptable doses, but it may also be to isolate and find suitable preparations of the substance.[40] Such specialised companies normally only perform clinical trials and usually on behalf of the big pharmaceutical companies in need of specific competence for their clinical trials or in need of resources. The actors performing the trials have as a rule a large scope of freedom to handle these in their own way. There are seldom any specific directions made by the big companies that the performers of the trials have to follow. The overall strategies of the project are though in the decision of the purchaser of the trials.

3.3 Post-market

3.3.1 Registration aspects and consequences

The pre-market stage ends with the clinical phase and the post-market stage takes over. A drug must be registered in each market where it is intended to be sold. An official authority in each country has to give its approval before the drug can be commercialised in that specific country. Therefore the post-market starts with a New Drug Application (NDA), which is an application for registration of the new drug. NDA is what the application is called in the US when the filing is being made to the United States Food and Drug Administration (FDA), but the term is normally used to describe the application to get a new drug approved in whichever country or authority concerned. The basis of this application is the results from the three phases of clinical studies. This documentation is often very extensive.[41]

Until recently an application for registration has been necessary in every country where you want to market a new pharmaceutical product[42], but now it exists within the European Union (later referred to as EU) a medical authority which is common to all the member states, the European Medicine Evaluation Agency (EMEA). An approval of an application for registration granted by the EMEA is valid in all the member states.[43] After the registration the pharmaceutical company can begin to produce, market and sell the new drug.

3.3.2 Clinical trials continue

Clinical trials on humans continue even after the registration of the drug. This is the fourth phase. These trials can take place as long as the drug is on the market. One of the purposes to continue to do tests even after the market-introduction is to find new or expanded application areas or indications for the drug.[44] Another purpose of the tests in phase four is to make sure that the company selling the drug is always ahead in knowledge of the drug. It is very important to have a good documentation of the drug and its effects in case of an accusation from competitors or other actors in the business. For example it is vital to obtain immediate knowledge of any adverse events, meaning any unintended and unfavourable sign, symptom or disease associated with the use of a pharmaceutical product. This is an essential competitive advantage.

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[40] Domeij, pp 16
[41] It can exceed 100 000 pages.; LIF, 1998, p 24
[42] In Sweden the official authority is the Medical Products Agency (Läkemedelsverket)
[43] LIF, 1998, p 24
[44] Eliasson, p 151; Bergenheim, p 18; LIF, 1999; p 11

3.3.3 Production and marketing – the product enters the market

When a drug has been registered in a country it is vital that the drug enters the market as soon as possible. It is important to launch the product rapidly in the market in order to benefit from the proprietary position the intellectual property rights give the owner of the product. During this period, when there are no competing generic products in the market, it is possible to build up a strong brand and have an opportunity to get paid for the expenditures made in connection with the discovery and the development of the drug.

Before the new drug has received a reputation the sale is usually relatively slow. This is because the quality, characteristics and effects of the product are uncertain to the persons prescribing the medicine in the medical area as well as to the consumers. The sale will increase rapidly when and if the quality of the product gets a good reputation and it will continue to increase until all the potential consumers are being reached. When new and better drugs enter the market, there will be stagnation in the sale of the product. As a consequence of the end of the patent protection period there is also a competition in the form of generic drugs, which use the former protected active substance in their products.[45]

The next step in the commercialisation process following pre-clinical and clinic trials is production and marketing. After the major development process has been completed, the costs for production and marketing are the most important running variable expenses. The test production of the future product started early in the development process, but it is not until the moment when the product is about to be launched that the real production activity starts.

The company that commercialises the drug can choose either to produce it in-house or to outsource the production. There are firms specialised in only producing drugs developed by others. There can also be two different manufacturers of a drug, where one produce the active substance(s) and the other takes care of the substance to transform it into a form that is suitable for the future consumers. This latter type of manufacturer often plays an important role because it is a technique itself to develop the best preparations of a drug, which gives the substance the right effect in the body and makes it possible to take in.[46] The company commercialising a drug has an interest in selling the best preparation possible of it and if the company is unable to develop such preparations by itself an option is to outsource this work to a specialist.

The expenditures related to production are negligible in comparison with those spent on R&D. Thus the efficiency of production is not that important to a company as it is of R&D and marketing. All large pharmaceutical companies have in general their own factories where they produce their products. Among smaller companies it is though much more common to outsource the production to contractual manufacturers.[47]

Even when a finished product is developed and it has entered the market the companies in the pharmaceutical industry still have an interest in cooperating with each other. Such cooperations can have different expression. Agreements relating to marketing of pharmaceutical products are very commonplace. A company can for example have as its policy not to deal with marketing and/or distribution. All companies do neither have their own

[45] Bergenheim, p 33
[46] Vedin, meeting 2000-09-27, www.neopharma.se, 2000-11-01
[47] Bergenheim, p 23; NUTEK, p 98

marketing establishments in every country where they market their products. For this reason they enter into agreements with local companies that take care of the distribution and/or the marketing. A certain country's political situation, legal system or trade and tariff barriers can also affect the choice of a company whether to act independently or through a licensee or an agent or another middleman.[48]

Most large pharmaceutical companies have a few leading products, which contribute to the major part of the companies' income. Such successful products that sell in enormous quantities are often called "blockbusters".[49] An example of a blockbuster is AstraZeneca's Losecä , which for several years has been the best selling drug in the whole world.[50] The companies are very dependent on their best selling products and therefore it can be critical for the company when there is a decrease in the demand of such a product.[51]

There is a very keen competition in the drug-related pharmaceutical industry. The effective patent protection time of a drug is relatively short and new better drugs are continuously developed. Both these phenomenon contribute to a decrease in the demand of older drugs. For this reason it is important to regularly launch new competitive products. If the ten largest pharmaceutical companies in the world want to hold their market position they need to introduce five new products per year having a sale potential of 350 million USD each. During 1990-1994 these companies where only able to launch half such a product in the market each year.[52] This shows how difficult it is for these large companies to come up with new successful products.

Recently the marketing strategies of the pharmaceutical companies have been observed in the media. People in the business, such as doctors, are daily receiving a lot of leaflet folders from companies. These companies also tempt with different kinds of rewards, such as travels, gifts, etc., if the medical practician chooses their product. The companies arrange marketing and education days when the people in the business are invited for free to participate. Assiduous advertising has shown to be effective and necessary. The costs are huge for a developing and producing pharmaceutical company and of course they must find a way to finance their activities and make profit. With these facts in mind advertising is necessary. The keen competition situation has resulting in advertising becoming an even more important means of competition.

Even if a company has not succeeded in developing new products of his own, there is still a need of new marketable products in its assortment. To compensate the lack of own-developed products a solution is to sell products developed by others. It also makes the company less sensitive for variations in its own product development. These are reasons why it in the pharmaceutical industry is common to enter agreements with competitors. One frequent agreement is co-marketing, which means that two competitors market the same product but use their own trademarks. Often this is done as an exchange of products in a cross-license agreement.

Another means to compensate a lack of products is to enter into an agreement to market

[48] Hodkinson, p 207
[49] Stankiewicz, p 111
[50] AstraZeneca, Annual Report 1999; NUTEK, p 99
[51] For some of the major companies it is only three products that represent 70-80% of their total sale. (Bergenheim, p 26)
[52] NUTEK, p 91

another company's product. This is called a co-promotion agreement and is a type of license agreement. In this type of arrangement there is an obligation to use the trademark of the original owner of the product, in this case the licensor. Such an agreement can be negative for the party obtaining the product, the licensee, because it exposes its rather weak position.[53] The positive aspects of the arrangement, such as increased income, may though neutralise the negative ones.

4. The objectification process

4.1 The objectification makes it possible to commercialise knowledge

The pharmaceutical industry is very knowledge dependent. Knowledge is the basis for the whole development process of pharmaceuticals as well as for their commercialisation. Knowledge as such is an abstract and fleeting mass of information without any determined shapes or bounds. This distinctive character is however by no means preventing knowledge of being an asset, but to become an asset certain measures are required.[54]

Before any commercialisation of knowledge can take place it must be objectified. The objectification of knowledge has the effect that the knowledge then is regarded as an independent feature that can be commercialised.[55] Through such an objectification knowledge can become an intellectual property, thus a property that can be transferred or licensed. The most important intellectual property for the pharmaceutical industry is patents. Besides patents, know-how as an intellectual property is of great importance to the industry. The protection of knowledge as know-how is though much more delicate. The reason for this is that what is protected as know-how must be kept secret and this is not possible for knowledge in end products that are sold in the market. If a product does not have patent protection "free-riders" can easily copy existing pharmaceuticals and thus benefit from innovations and developments made by others without having the costs for it.

Besides the possibility to objectify knowledge as intellectual property, such objectification can take place through agreements. The most important agreement in the pharmaceutical industry is the license agreement but others, such as collaboration and secrecy agreements, are also common. In an agreement with knowledge as its object, it is the definition of the object that represents the objectification of knowledge. It is for the best if the object is precise and well defined. The parties must have the same opinion of what the object of the agreement is and this definition of the object should also be clearly defined in the agreement. This is a way to avoid unnecessary disputes.

4.2 Knowledge strategies

For the actors active in inventing and developing in the pharmaceutical sphere there are three possible strategies how to conduct oneself to the developed knowledge and an eventual commercialisation of it. These are to patent the knowledge, to keep it secret and to make it publicly known. The strategy the most appropriate depends on the type of the knowledge, its field of use and the developer's purpose with it. Other factors affecting which strategy to

[53] Vedin, meeting 2000-09-27
[54] Petrusson, unpublished draft, p 172
[55] Petrusson, unpublished draft, p 177

choose are the environment within which the actual knowledge is found and which actors that are involved in the production of the knowledge.

4.2.1 The Patent Strategy

The patent strategy is the main strategy used for pharmaceuticals. This is no accidental occurrence. Both patent applications and granted patents are means by which important knowledge is objectified and packaged as intellectual property. After the completion of such activities the knowledge can be exploited and yield a good return. The legal aspect of objectifying knowledge as a patent is that a patent creates property that can be transferred and licensed. The knowledge has thus through the objectification become an object with a capital value which can be commercialised.[56]

When competitors can get access to the knowledge, the patent is often the only suitable protection.[57] One way in which competitors can achieve information of the knowledge is through documentation of the invention filed with governmental authorities. Another means can be through the market introduction of a pharmaceutical, if the knowledge in such a product is easily accessible by analysing the product. Such an analysis is called "reverse engineering". Since national and international regulatory authorities get access to information, through IND- and NDA-applications, that otherwise would be regarded as confidential, a patent of a pharmaceutical invention is indispensable.[58]

Not all knowledge can though be patentable. The knowledge must consist of an invention that has an industrial application and involve an innovative step. It must also be new from what is earlier known and it must be useful. If the knowledge can be patentable, the patent gives a strong protection. It gives the owner a proprietary position for a limited period, under which he independently can use the patented knowledge or give others the right to use it in return of remuneration.

The protection time for a pharmaceutical after it has entered the market is normally 10 to 15 years depending on how long the development process has taken before the product is completed. This period is including the extra protection period that now is possible for pharmaceuticals in at least the US, Japan and the EU. The extra period was introduced because the effective protection period for pharmaceutical patents was considerably shorter than that of patents in other technical fields. It is only one patent in a protected product that can be object of the extra period and this period is maximum five years. The owner should therefore carefully consider which patent of a product that is the most useful and important before applying for the extra period protection.[59]

This opportunity to obtain an extended protection period must be regarded as something positive for the pharmaceutical industry, because without it the effective protection period should be very short and not in agreement and proportion with the costs spent on the development process. Furthermore other technical industrial areas dependent on patent protection would be in a more favourable position if the extra period of protection did not exist. This would result in an undesirably unequal situation within industries where patents are important.

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[56] Petrusson, unpublished draft, pp 170
[57] In Sweden patents are regulated in the Patent Act, SFS 1967:837.
[58] SOU 1998:50, p 71
[59] LIF, 1998, pp 33; Koktvedgaard, p 255; EEG 1768/92, Art 13

Even if the scope of protection of the patent is defined in the patent claims of the application, the scope is not definitely determined at the time the patent is granted. The patent can though be regarded as an assumption of a certain protection position. How wide the extent of the protection for a certain patent actually is will thus be determined in the meantime the patent is practised and used in its relevant pharmaceutical field. The patent cannot be regarded as definitive because it can be declared invalid and the extent of the protection can turn out to be more restrictive than assumed. Such circumstances can have unexpected and not desirable consequences for the holder of the patent. He can have made enormous investments in a project that relies on a certain patent and if the patent then turns out to be void or the scope of it is not as he had thought, the holder has to accept that other actors use the knowledge in a way that otherwise would have been an infringement of the patent. This can have severe economical effects on a patent holder.

In order to prevent that the patent is void or that it has a more restricted scope of protection it is vital to be very observant on the importance of a well-considered and formulated patent application. When the applicant has a choice whether to let the patent office perform a more or less exhaustive investigation of patentability of the invention, it is advisable to choose the most exhaustive one. Such an investigation is more time demanding and expensive, but it is however to recommend since the applicant will, if he is granted a patent, have better knowledge of the status and the scope of protection of his patent than he otherwise would have.

It is very expensive to obtain and to maintain a patent. The costs for filing an application and the maintenance of a granted patent are huge. Besides these costs there are large expenditures for patent agents, who often are indispensable for the holder of a patent. Today the market of pharmaceutical products is global. It is therefore almost necessary to have a global patent protection for pharmaceuticals, irrespective of whether the patent holder is a large international company, a small national one or a researcher. The situation of competition is very keen in the pharmaceutical industry and there is always a risk that other actors will copy an invention and commercialise it in countries where the owner has no protection. This makes it often essential for even a small company to obtain a wide territorial protection. Seeing that patents are national the cost for having a wide and well covering protection is enormous.

Patents can protect a pharmaceutical in different ways. The product in itself, the method to produce it and its medical indication are patentable.[60] Novel chemicals and discoveries can be patentable, but to what extent depends on a number of different factors. If it is a new substance that is not previously known in the nature, product and process claims of protection can be done. But if the discovery is something already existing in nature the patent ability is depending on whether an application to practical use of the discovery can be shown. Concerning pharmaceuticals and methods of treatment, the European Patent Convention (EPC) states that an invention of a method of treatment of the human or animal body shall not be seen to be capable of industrial application and is thus not patentable. However where a pharmaceutical product is to be used for diagnosis or tests, a claim for patent protection can be drafted without any difficulty provided that it is a novelty and has an inventive step.[61]

Protecting knowledge as patents has many advantages. A disadvantage may though be that the protection is limited in time and that the information over what is protected gets publicly

[60] Koktvedgaard, p 208
[61] Hodkinson, pp 140

known and accessible through the granting of the patent or 18 months[62] after the application has been received by the official authority. This is of course also an advantage since it can lead to progresses in research that can be vital for humanity. The application is published after 18 months even if a patent is not granted. It is therefore not a good idea to apply for a patent if there is an uncertainty whether patent protection will be obtained. If a patent application has been filed and it, during the turnaround time of the application, seems likely that a patent will not be granted it is a good alternative for the applicant to withdraw his application before the 18 months have passed. Through the withdrawal the invention avoids getting publicly known and can be maintained as a secret.

Even though patents as a protection for immaterial property may have its disadvantages, it often is the best and only mode of protection for pharmaceutical end products. The major advantage is its protection of investments in new knowledge. An advantage of patents is also, for the holder of the patent, that independent creation is not a defence in a patent infringement dispute. This means that the patent gives the owner of an innovation a more complete power of exclusion regarding other innovations than the other intellectual properties, such as copyright, design and trademark, give.[63]

For a pharmaceutical company being the proprietor of knowledge developed by its employees a patent can have another positive aspect as well. By applying for a patent the company is thereby the holder of the knowledge meaning that the knowledge is no longer tied only to the employed inventor(s). The researchers can thus no longer without limitations use their invention. An approval of the holding company is required.[64]

4.2.2 The publishing strategy

This strategy is not frequently used within the pharmaceutical industry. It may though be interesting if the knowledge is not worth to protect through a patent because the costs of such a patent would exceed the economical benefits of it. In order to prevent that someone else patents the knowledge and takes advantage of its value, the knowledge can be published. This prevents the knowledge from being patented since it then is regarded as publicly known.

When the knowledge has been publicly accessible it is free for everyone to use. The inventor then has the same right to the knowledge as everyone else. This means that the inventor cannot accuse anyone using the knowledge for infringement. Another consequence of the knowledge being free is that the inventor will not make any profits in others usage of it.

4.2.3 The secret-keeping strategy

Compared with the patent strategy this one is much less expensive and the period of the protection is unlimited. Secret information can have a legal protection as a trade secret. A trade secret gives a good protection of knowledge as long as it relates to information that can be kept secret. As a consequence of the nature of the protection, that the information must actively be kept secret, trade secret as a protection is not suitable for all types of knowledge. It is the fact that the knowledge is secret and unknown to others that gives it its value.[65] The fact that it is secret also prevents other actors from using it.

[62] Art 93 European Patent Convention; 22§ The Swedish Patent Act (Patentlag (SFS 1967:837))
[63] Anawalt, p 382
[64] Petrusson, unpublished draft, p 185
[65] Anawalt, p 169

Keeping the knowledge secret is not always an alternative to patenting, since not all knowledge easily can be kept secret. If others can get access to the knowledge, such as through analysing pharmaceuticals, it is not possible to keep it secret. For this reason trade secret as a form of protection is not suitable for knowledge included in an end product that will reach consumers (and competitors). Trade secret is therefore more appropriate as a protection when it comes to technologies for developing pharmaceutical products, since these more easily can be kept secret. This means that though trade secrets as a protection for intellectual property may have some advantages over patents, it is not an alternative to patents for the pharmaceutical industry; it is rather a supplementary protection. The holder of knowledge does though not have to choose either to patent or to keep secret. Most often these two strategies are present together as modes of protection for the same mass of knowledge.

In some cases keeping knowledge secret can be an alternative instead of applying for a patent. This may be the case if there is a risk of obtaining a patent with a scope of protection the applicant finds too limited. The costs for obtaining the protection may exceed the commercial value of it if the protection becomes restrictive. If the knowledge can be kept secret is though always, as mentioned above, depending on the type of knowledge in question. Keeping knowledge secret can be risky, since someone else then can patent it. Even if someone obtains a patent the secret keeping actor maintains a right to continuously use the knowledge though he cannot sell it or let others commercially use it.[66]

Trade secrets, such as know-how and undisclosed information, are protected both in international conventions and by national law. The state parties of the World Trade Organisation (WTO)[67] are all required to have a protection of trade secrets due to the TRIPS agreement.[68] Within the EU such secret information is regulated in a competition perspective. One of the main goals of the EU is to establish a free market with free trade for merchandises. In order to prevent that the competition rules of the EU not will hinder the exploitation of new knowledge and restrain commercialisation with it, a regulation[69] has been introduced concerning knowledge transfer agreements. This regulation allows certain knowledge transfer agreements, which are considered to favour the goals of the EU. Without this regulation these agreement would be regarded as limiting the free competition.

In Sweden the protection of trade secrets, which include confidential information and know-how, is secured by a regulation called The Company Secret Act.[70] Its purpose is above all to protect companies from outsiders attacking the company's internal knowledge mass. Such undue actions can consist of company espionage and unauthorised exploitation or exposure, which results in competitive damage for the company attacked. The company secret regulation is thus aimed at certain activities and is not protecting the company secret as such.[71]

In order to maintain the knowledge secret the owner of it must actively and effectively take reasonable efforts to secure the secrecy of it. In an eventual dispute the owner must be able to

[66] Petrusson, unpublished draft, p 45 &pp 101
[67] The WTO has at present 141 member states and still more are negotiating for a membership. (www.wto.org, 001211)
[68] TRIPS means "Trade Related Aspects on Intellectual Property Rights" and is one of the base agreement of the WTO. Trade secrets are regulated in its Article 39.
[69] Regulation 240/96, 1996-01-31
[70] Lag (1990: 409) om skydd för företagshemligheter
[71] Helgesson, pp 355; Sandgren, 1995, p 32

show that he has identified the knowledge and that he has effectively tried to keep it secret. Without such efforts on the behalf of the owner, a court will be unwilling to protect the knowledge. Furthermore the owner must be able to demonstrate that he has spent time, effort or money to develop the knowledge. If the owner is a company it is a good idea to make the employees sign a secrecy agreement concerning the knowledge it want to remain secret. It is also of importance that the employing company has education and information programs regarding secrecy issues.[72] It can also be valuable to have a explicit policy defining how the company will maintain knowledge secret.

In accordance with the European Community (EC) regulation, knowledge must be secret, substantial and identifiable to be regarded as confidential and achieve protection as a trade secret. The TRIPS agreement also states that information must have a commercial value to be protected.[73] Knowledge is considered as secret if the information is not known in the public domain or publicly available. To be substantial the information has to be useful and the information must also be sufficiently identified. Means to identify knowledge may be done by description in an agreement or otherwise by documentation.[74] When the knowledge is defined in such a way it is objectified and can therefore be seen as an asset.

If the requirements commented above are met know-how can be regarded as a trade secret. Know-how is some kind of technical or other information, including documentation containing know-how, which is not in the public domain and which is concerning the whole business of the company. Examples of what can be considered as know-how are descriptions of manufacturing methods, recopies, formulas, models or patterns.[75] In an agreement it is normally clearly defined which meaning know-how or confidential information shall have as well as the anticipated content of these notions. These definitions are found in the beginning of the agreement in order to describe the notion and to facilitate the further reading of the agreement. Below we have an example of a definition of know-how, found in an agreement:

> "Know-how shall mean technical and other information which is not in the public domain, including, but not limited to, information comprising or relating to concepts, discoveries, data, design, formulae, ideas, inventions, methods, models, assays, research plans, procedures, design for experiments and test and results of experimentation and testing, including results of research or development, unless being subject to published patent rights, including manufacturing processes, specifications and techniques, laboratory records, chemical, pharmacological, toxicological, clinical, analytical and quality control data, trial data, case report forms, data analyses, reports, manufacturing data or summaries and information contained in submissions to and information from ethical committees and regulatory authorities."

In the quoted agreement the notion of know-how was first explained and later on it was stated that transferred know-how is confidential and should be kept secret. This is a usual practice in agreements where know-how is transferred between parties. As the quotation shows such definitions are often long and detailed. Since there usually are many actors involved in developing pharmaceuticals confidential information must often be transferred between different actors. This requires a good regulation of confidentiality matters in agreements.

Protection of knowledge as a trade secret is common in the discovery process and in the beginning of the development process of a pharmaceutical. The importance of trade secret

[72] Anawalt, pp 173
[73] Art 39, the TRIPS agreement
[74] Anawalt, p 171; EEG 240/96, 1996-01-31
[75] EEG 240/96, 1996-01-31

does not diminish when a patent protection is granted. Actually its importance increases as the development proceed. This is because the more research that is performed the more know-how will be generated round the innovation. Patent is thus the principal protection and trade secrets are more of a complement.

4.3 Objectification of knowledge in the R&D phase

In the very beginning of the discovery and development process the knowledge consists in personal skill and research notes. When the owner of an invention wants to patent it, it is important to file an application early while the invention is unknown and new. On the other hand it can be advantageous to wait until there is more certainty of what to patent. If the owner waits too long there is though always a risk that someone else already have patented the same invention. These two are important factors that always must be weighted against each other.[76] Within the pharmaceutical industry a patent application is filed very early, actually as soon as a chemical combine with potential is found. Of the filed applications there are many that are not worth protecting and therefore a lot of patents protecting inventions will never be used commercially.

4.3.1 Researchers in the academia

Researchers within the academia are as a rule not capable or even willing to perform the development process that will follow after basic discovery and research. They have thus an interest in finding actors with competence, facilitates and financial resources to do the further development work. The main interest of these researchers is to obtain capital to be able to continue performing research and thus they commercialise their invention in an early stage. Normally they are not interested in commercialisation activities that may take place in the later stages of the development process of the invention.

The researchers are though not indifferent in their choice of partner taking over their developments. They search for the actor that is most capable of commercialising their innovation in order to become useful products with high quality. To receive a large compensation is thus not the conclusive evidence in the choice of a partner. The researchers do not normally search for a specific type of actor. They can do business with a lot of different type of actors, such as individuals, organisations, profit-driven companies and non-profit research institutions. They often prefer to find one interested party instead of negotiating with several.[77] The intermediary firms have as their function to take care of innovations developed within the academia. It is therefore quite natural that the researchers approach such a firm in their search for a partner. It may be the case that researchers in general rather turn to small firms than to larger ones when they want to sell or license their technology.

A key question is now how the inventor shall approach a party interested in taking over the project without loosing any rights or getting used in an unprofitable manner. Sometimes there is already an actor connected with the research, which may become a potential commercialising actor of the research results. Such an actor can for example be a sponsor or a research collaboration partner. If no such actor already is involved in the research the researcher must actively find a potential partner. The experienced inventor is very aware of the existing pitfalls when contacts with a big company are in their initial stage. Caution must

[76] Petrusson, unpublished draft, p 51
[77] Council on Governmental Relations from 1993-11-30, www.cogr.edu/qa.htm, 2001-02-03

be used in order not to disclose any relevant secrets, connected with the new developed knowledge, to the big company. If there is a leakage of secrets and no protection is at hand the inventor is going to do a loss that can be very unpleasant. If others, which are not tied to any secrecy obligation, have got access to the knowledge, the researcher looses his propriety position to the knowledge. The value of the knowledge decreases and the chances for the researcher to earn money on the knowledge have most likely disappeared.

When the researcher shall approach potential companies for negotiations he can act in different ways. It is an advantage if he has already filed a patent application, which he can combine with a secrecy obligation for the company, regarding essential know-how surrounding the patent pending. The researcher may start by sending a non-confidential document over the innovation to actors likely to be interested. Otherwise he may more informally just contact companies or other actors that he believes are interested. His way to act depends on whether he has had contacts or collaboration with certain actors earlier. It also depends on if and which informal network he has with persons within the industry. If a contacted actor shows interest, this relevant actor has to sign a secrecy agreement prior to receiving confidential information. Through such actions the researcher obtains a more secure position in relation to the party he negotiates with. It is also an advantage if the researcher can negotiate with several companies at the same time, since this increases his chances of receiving the best possible offer.

If the researcher has not filed a patent application he must insist that the companies interested in negotiating sign a secrecy obligation before any discussions take place. His knowledge is then protected as a trade secret. It is normally no problem in having a company signing a confidentiality agreement. Companies are no longer interested in using researchers in order to obtain and exploit their knowledge without respecting the rights of the inventors. The companies have realised how important these researchers are for the innovative and creative activities in developing pharmaceuticals.[78]

The researcher can also entrust an independent honourable person his invention before he enters into discussions with any interested party. This can be an alternative when negotiations with potential partners shall take place and no secrecy agreement is signed. Such an entrustment shall be written, signed and testified. The function of this entrustment is that a third party knows of the invention and the company can then not assert the invention as theirs. This prevents the company from unauthorised usage of the invention.

If the receiver still has an interest in the innovation after he has got access to confidential information about it, the parties will continue with a negotiation of an agreement. This is irrespective of how the researcher previously has approached a potential partner. The negotiations may result in a letter of intent, an option or a license. Each of these can be combined with a research agreement, where the researcher continues to develop his research on the innovation.[79]

The researcher can choose either to sell or to license the invention. If he chooses to sell the invention he has no further rights related to it. The normal payment to a researcher selling his invention in an early stage would be a lump sum. He can even be remunerated by milestone payments or by a royalty provision. These types of payments can also be combined. If the researcher is paid with a lump sum he is not affected by any of the risks connected with the

[78] Petrusson, unpublished draft, p 200
[79] Council on Governmental Relations from 1993-11-30, www.cogr.edu/qa.htm, 2001-02-03

further development of the invention. This can both be of an advantage and a disadvantage. If the invention is successfully developed the lump sum can turn out to be unprofitable. But if the development of the invention is not that prosperous the lump sum agreement may turn out economically well. When the company totally takes over all risks connected with the development of the invention, the remuneration they give to the researcher is always lower than it otherwise would be.

A researcher can find it more appropriate to license his knowledge. In this case he maintains the rights to his knowledge. He can then choose whether to grant an exclusive or a nonexclusive license. A nonexclusive license is likely to be granted for a patent with a wide scope of application that can be used in multiple industries. A license with an exclusive field of use can also be an alternative for this type of patent. An exclusive license is more frequent for patented innovations that require large private investments before they can enter the market. For innovations that still are in an undeveloped stage and need investments to find out their potential and utility, the exclusive license is the most commonly used.

The companies are naturally more interested in an exclusive license and are also willing to pay more for such a license. The best option for the researcher should be to find a partner that has the resources to commercialise his invention on a global basis. The most common way to compensate a researcher granting a license is by the combination of milestone payments and royalties. These payments and royalties are seldom large, since the innovation is yet relatively undeveloped and risky. In the US the royalty rate is usually in the three per cent to six per cent range and it is based on net sales. There are several different factors that affect the size of the payments and royalty rates. Such factors are the type of technology, its stage of development, the size of the potential market, the profit margin for the anticipated product and the amount of perceived risks.[80] How much the researcher will earn on the licensed knowledge depends on the future development. If this development turns out successful he will get better paid. The researcher shares though a part of the risks involved with the development with the licensee.

A license often gives the licensor a bigger possibility to influence the development of his knowledge. By affecting the content of the agreement during the negotiation phase he can see to that he will get involved in the future development and be informed of the licensee's activities. The agreement can for example state that the researcher shall get information about the development progress and results at certain intervals or that he shall take part in certain decision, such as in which countries patent protection will be applied for.

Whether the researcher chooses to license or to sell his knowledge depends on to what extent he wants to maintain control over his knowledge, but it can also depend on the type and the scope of the knowledge. What risk he is willing to take is also of importance to his decision.

It is commonplace that researcher in the academia are being sponsored in their innovative work. The actors sponsoring them can be pharmaceutical companies, research firms or public or private foundations. Public sponsorship is as a rule for the promotion of research as such while private sponsorship is more focused on economical gain. There is a tendency in the academic sphere towards awareness concerning caution in the treatment of innovations and new knowledge developed therein. The researchers have also realised their importance for the development of new pharmaceuticals and their possibility to receive economic support. A

[80] Council on Governmental Relations from 1993-11-30, www.cogr.edu/qa.htm, 2001-02-03

good reputation of the researcher and an interesting and innovative image of the research are an advantage to attract financiers.

In private sponsorship it is normally the sponsoring actor that will obtain intellectual property rights to the sponsored research. This will be regulated in an agreement between the researcher and the sponsor. The researcher should in such an arrangement guard his interest carefully and he could demand a certain percentage of the future profit or a share in the intellectual property. A sponsor could at his part inspire and spur the researcher by offering a share in the future income or in the intellectual property. It is a matter of fact that encouragement and reward have a stimulating effect on the receiving person.

4.3.2 Research companies

As the single researcher the research companies are active in the discovery and the early development process. Normally they are present in the process during a longer period than the researcher in the academia. These firms can develop knowledge by themselves or buy interesting new knowledge from researchers or other firms. Such research companies can for example be a drug discovery firm, a start-up or an intermediary firm.

These firms are normally much more patenting strategic than the researchers in the academia. They know the value of patents and the importance of a strong protection of their technologies and knowledge. These actors apply for patents before they try to find a partner that will take over and complete their projects. When an invention has its origin within the company or is bought from a researcher the company is the holder of the patent. Their aim is to license their rights to patents and knowledge to larger pharmaceutical actors at the best possible terms. Small research firms are important to the large pharmaceutical companies as supplier of new projects and ideas and this is a fact the research firms are often well aware of. They are therefore in a strong negotiation position if their offer is competitive and attractive.

The small research firm is not necessarily developing projects totally by itself. Sometimes they enter into cooperation agreements with other actors. In this type of arrangements the distribution of risks and of financial and physical contributions are regulated. These cooperation arrangements may be interesting for the research firms since they tend to lower the risks connected with the development. Another advantage is that the firm gets access to new competence and knowledge, which is in the possession of the other party. The parties normally own inventions made within such an arrangement jointly. If the parties of the cooperation are two research firms their strategy is to license their joint patents and knowledge. But if the counterpart is a pharmaceutical company this party takes as a rule over the project when it comes to the later stages of the development process or to the marketing phase. The research firm then grants a license of its part in the joint patents to the other party.

The research firm can, as mentioned above in the presentation regarding researchers, act as a sponsor of researcher within the academia. This is done when the firm finds a research project in the academia interesting that relates to the firm’s research sphere. The research firm may though also get sponsored, and then the sponsor is a pharmaceutical company. Such sponsor arrangement can be a means to finance the firm’s research. It can also be a means to find a commercialising partner.

Sometimes a new company is established on the basis of a technology or an invention a researcher has made, such firms are often called start-ups. The researcher has to find persons

or actors interested in investing and participating in the further development that will take place within the new company. These persons and actors want as a rule something in return of their respective contributions. The consequence is that the researcher has to assign at least some parts of the rights he has to his technology. This is the case even in a sponsoring relation, but to find one or several sponsors can be of a great importance and diminish the fact that some proprietary right have been forsaken. An alternative for the researcher that wants to maintain his rights can be to grant an exclusive license to his rights to the company. He then maintains the ownership, but the exploitation of the invention lies totally within the hands of the licensee. The advantage for the researcher is that if the exclusive license agreement is terminated he still has the possibility to find another exploiter of his invention.

It is often during the period from filing an application to the granting of a patent that the applicant has the strongest protection. This is because he then has a certain time under which he is free to choose where he wants protection. It is the uncertainty concerning the protection he will obtain that makes his position strong. The competitors and other actors in the market are uncertain on which protection the applicant will obtain and they do not know what the new invention actually represents. During this period the applicant often has a strong negotiation position, if he for example wants to negotiate with an actor interested in becoming a licensee. If an application is made within the PCT[81] system the applicant can choose among more than 90 countries. The PCT application therefore gives the strongest negotiation position. For a research firm that does not have sufficient resources to obtain a wide territorial protection a PCT-application can be a good alternative. He then has a certain time under which he can negotiate with potential partners. The party that obtains the license will then decide in which countries patent protection will be applied for.

The small research firm owning exclusive rights to an innovation, which possesses development potential sends prospectus to several pharmaceutical companies. The content of this prospectus is non-confidential and is only a short description of the firm's offer. The research firm is aware of its importance to the pharmaceutical company as a supplier of new knowledge, since these companies always is in need of new products, and this makes its position relatively strong.

If a pharmaceutical company shows an interest in the received prospectus the parties write a secrecy agreement before any confidential information is disclosed to the pharmaceutical company. This agreement is often called a CDA, Confidential Disclosure Agreement. Another type of secrecy agreement is the MTA, Material Transfer Agreement. In this agreement the material transfer of a substance and the like combined with secrecy obligation is regulated. The small research firm can negotiate with several pharmaceutical companies at the same time and a CDA agreement is then signed with each party. The companies the research firm negotiate with do not necessarily have the same nationality as the firm. As a rule it is to the contrary because the small research firm aims at finding a global partner that can handle an international commercialisation.

If the negotiations are successful and results in an agreement, this agreement in general includes granting of a worldwide exclusive license. This is often the most desirable solution for both parties. For the research firm the exclusive license generates more money to the firm and it can facilitate to have just one partner. Since it means more work having many licensees, the research firm often licenses several projects to the same licensee. As a rule the firm do

[81] The Patent Cooperation Treaty (PCT) is an international convention which gives an opportunity of a coordinated application where many countries can be designated at the same time.

though have a number of partners in order not to become too dependent on a certain partner. If the licensee the research firm is very dependent on gets a bad reputation and badwill, the research firm will be highly affected even though his licensed objects not are the reason for or even not connected to the bad reputation. It is therefore a good idea to have several commercialisation tentacles.

4.3.3 Pharmaceutical companies

The pharmaceutical companies perform own R&D, but they also buy and license in patents and knowledge from the academia and from research firm. Their dependence on external resources to develop new products has increased over the years.[82]

These large firms are very well aware of the importance of knowledge and they know how to protect and preserve their knowledge. They have clearly defined policies concerning know-how and confidential information issues. The employees, especially those working with R&D, are thus very informed of the kind of knowledge that is classified as secret and how they shall conduct themselves to this information. A big pharmaceutical company is taking measures to delimit as much as possible the number of persons with access to secret knowledge. The larger this group is the higher is the risk that secret knowledge will be disclosed to someone not bound to any secrecy obligation. Such leakages can cause a lot of damage because the secret knowledge can come into the hands of a competitor or become publicly known. The competitor can then take advantage of the new technique or knowledge and if it gets publicly known a patent cannot be granted anymore. The knowledge therefore looses its value to the company at the moment it is disclosed in such a way.

It can be very difficult to distinguish all different types of knowledge and other information that should be regarded as confidential. Confidential information has for this reason to be well defined. It is thus extremely important that those with access to the secret knowledge are aware of the confidentiality of it and how to handle it. The major mission for the company is to actively take necessary actions to keep its knowledge, which is considered important, secret. This can for example be done through verbal information or through written secrecy agreements. Every time contacts are established with external persons that will contain some kind of disclosure secrecy actions will take place. External contacts are frequently occurring which means that confidential arrangement have become a routine measure.

An example of a definition of confidential information in a license agreement can be as follows:

> “”Confidential Information” shall mean any and all information of or about a party including all information relating to any technology, product, process or intellectual property of such party (including, but limited to, owned or licensed intellectual property rights, data, know-how, samples, technical and non-technical materials, and specification) as well as any business plan, financial information, or other confidential commercial information of or about such other party. Not withstanding the foregoing, specific information shall not be considered “Confidential Information” with respect to such party to the extent that the other party possessing such information can demonstrate by written record or other suitable physical evidence that:
>
> a) such specific information was lawfully in such other party’s possession or control prior to the time such information was disclosed to such other party by the party to whom the information relates;

[82] NUTEK, p 92

b) such specific information was developed by such other party independently of the Confidential Information of the other party;
c) such specific information was lawfully obtained by such other party from a third party under no obligation of confidentiality to the party to whom such information relates; or
d) such specific information was at the time it was disclosed or obtained by such other party, or thereafter became, publicly known otherwise than through a breach by such other party of such other party's obligations to the party to whom such information relates."

A clause regarding confidential information was found in all agreements we have studied in which know-how was transferred between the parties. The example above can be seen as a typical example of such a clause. The textual content of these clauses may alter but the meaning remains the same. Especially the meaning of the four exemptions is the same in all agreements. The textual extent of the confidentiality clause varies a lot between the agreements, whereas the example above is a medium one.

As a rule it is the pharmaceutical companies that are the final links in the development process of a new pharmaceutical. They produce and introduce the product on the market and handle also the marketing issues. In order to fill up their constant need of new products these companies license in or buy patents and knowledge from external sources. These large pharmaceutical companies attract new ideas and projects almost like magnets and they get heaped up with prospects and offers from small firms and researchers wanting them to take over and develop their projects. Even if the situation is like this there is a keen competition between the pharmaceutical companies in order to attract and find the real breakthrough innovations. A researcher or a research firm that possesses such an innovation has therefore a strong negotiation position.

If a pharmaceutical company finds an offer interesting it has to sign a confidentiality agreement in order to receive more information about the offered innovation. The company then needs to evaluate the value of the patent(s) and/or knowledge contained in the offer so that an apprehension of the potential of the innovation can be obtained. This is usually done by a "due diligence" procedure. In this procedure the company analyses patents, patent applications and patentable innovations and the exact scope of the intellectual property rights. It is important to find out the ownership to patents, any contractual arrangements that the offeror has with others and if there are any intellectual property claims regarding the patents in question. A survey of data and tests related to the object of the negotiation is also included. To have a good starting point for further negotiations and to have a relevant opinion of the value of the offer it is vital to do the due diligence analyse thoroughly and well-considered. The due diligence procedure also contributes to define the object of the future agreement. [83]

If the offer is still interesting after the due diligence procedure the pharmaceutical company decides to continue to negotiate with the offeror. The next step is then, as a rule to sign a letter of intent saying that the parties shall negotiate to establish an agreement. This letter of intent is though not legally binding. Despite this letter of intent the offeror may discuss with several potential licensees or buyers. If the company wants an exclusive negotiation with the offeror it normally has to pay for this exclusivity.

A pharmaceutical company wants to have as much control as possible over the patents it has obtained the rights to through licenses. Therefore they want to have the possibility to influence the extent of the patent claims, the countries where patent protection shall be obtained or a possibility to take over the ownership of the patents if the licensor let them

[83] Petrusson, unpublished draft, pp 229 & p 236

lapse. The more control the pharmaceutical company can achieve over the patents the more value they have to it.

Besides performing internal R&D, buying or licensing in new knowledge, sponsorship a means to get access to new knowledge. The pharmaceutical company may sponsor a researcher, a research institute or a research firm. The direction of sponsored research is as a rule free. It is though not the sponsoring company that decides how it shall be performed or the program of it. In return of the financial support the sponsor wants access to the results of the research. Either the sponsor gets ownership in the results or otherwise he gets a right to use it.

4.4 Objectification of knowledge in the marketing phase

In this phase the development has resulted in a finished product that is marketable. The mission of the owner of a product is now to market it on the widest front possible in order to get paid for the development expenditures invested in the product. It is important that the product will get a good reputation on the market so it can be competitive. Since the patent protection period is limited it is vital to launch and market the product without delay.

A product can consist in many patents and these patents are in this phase already obtained. These patents objectify the knowledge the product is based on. All knowledge relating to the product is though not patented. Knowledge that cannot be and is not patented is considered as know-how. Such know-how is objectified through documentation made by the owner, through definition in agreements or through other types of clarifications. It is thus the knowledge packaged as patents or as know-how that is the asset for the owner.

Different types of license arrangements are, as in the R&D phase, also common in this phase. A license can be a means to spread the product in certain geographical areas where the owner of the product is not represented. It can also be a means to increase the assortment of products of the licensee. When it comes to marketing, the nonexclusive license is more common than during the development of the product. The nonexclusive license is appropriate when the product can be licensed to many licensees without a loss in commercial value occurs for the different licensees. The product then has to be a part of a competitive market where the choice of product of the consumers rather is based on brand or reputation than on the quality of the product.[84]

An owner of a product may choose to market the product himself in some geographical areas, while he in other areas prefer to grant an exclusive license. This license is then exclusive with a territorial limitation. The owner may also enter into distribution arrangements with actors in some or all areas where the product is sold. This is an option if the owner considers that such an actor has a better potential to distribute and sell the product in such an area than he has. The distributor buys the products on a fixed price basis. These distribution agreements are very commonplace. Another type of agreement used in the market phase is agency agreement. In this case the agent sells the products on behalf of the supplier of the products on a provision basis.[85]

Whether the owner of a product chooses to offer his product for sale through affiliates or branches or by means of a license, a distribution or an agency arrangement can depend on

[84] Bragg, p 65
[85] Nordén, Licens- och Distributionsavtal

many different factors. Which arrangement to choose often varies depending on the country concerned. Most large companies use several of these arrangements at the same time for selling their products in different countries or areas. Their choice can depend on if they want to have more or less control over the sale of the product. When an affiliate, a branch or an agent sells the product the owner of a product has more knowledge and control, because these legal entities are a prolongation of him.

The country concerned can affect the choice of marketing channel by different means. If the company owning a product has little knowledge of the commercial rules and the country's manners and customs is probably best for him to choose a local distributor, agent or licensee. A country's trade and tariff barriers, political situation or other trade factor may also affect the company's decision in such a direction. The license arrangement can be a way to enter a new market. The license is a form of cooperation, which can lead to a closer relationship between the licensor and the licensee. It also gives the licensor a certain amount of control on the market.[86]

When a company chooses a partner for the marketing of a product several considerations have to be done. The partner should have a market position, a reputation, resources and a product portfolio that suit the product of the company searching for a marketer or a distributor. To have a partner with a well-established and reliable sales organisation is also of great importance.

For a pharmaceutical company that wants to obtain a right to sell another company's product it is hence often important to have a strong patent portfolio and a good reputation. A company that own many and valuable patents and is of good repute is a more attractive partner. Since most large pharmaceutical companies always are in need of new products the cross-license is a common feature in the marketing phase. Sometimes the product are exchange between the two parties without any financial transfer is being made, but in some cases one of the parties, owning the least valuable product, has an obligation to pay a license fee to the other party.

The brand of a pharmaceutical is important. The brand is, just as the patent, an intellectual property giving its owner a propriety position. In contrast to the patent protection the protection period of the brand is unlimited. For a pharmaceutical company it is desirable to build up a strong brand around its product. A brand is also an object that can be transferred between parties, often by a license agreement. Brand issues are always regulated in license arrangement established during the marketing phase. When a company owning a product lets another company market this product, it is optimal for the owner if the company selling the product also will use the brand of his product. The owner then benefits from the goodwill established by the other party selling the product. It is then important for the owner of the brand to maintain control over how the other party is using his brand. If the brand is misused this can be of a great damage for the company connected with the brand and its reputation.

[86] Hodkinson, p 207

5. License agreements as a means to control commercialisation of knowledge

5.1 The signification of the license agreement

The license construction is the most important and utilised means to commercialise knowledge in the pharmaceutical sector. It is also used as a means to create strategic alliances, to build up networks and to get access to new knowledge. Licensing is very frequent in the pharmaceutical sphere ant the extent of it tends to increase even more. The main purpose for the licensee to enter a license agreement is to optimise his economical use and to profit from knowledge not developed by him. For the licensor the main purpose is to profit from knowledge he has developed by taking advantage of the licensee's resources. The licensor will also decrease the risks he otherwise would have had if he developed and commercialised the knowledge internally.

Through a license agreement a licensor gives a licensee permission to use something he otherwise would not have access to without infringing the proprietor's rights protected by intellectual property legislation. Consequently the licensee, through the license agreement, enters into a certain advantageous situation within which the licensor already is. It is the legal protection of intellectual property rights that establishes this advantageous and propriety situation. The agreement is the judicial tool whereby the licensee enters wholly or partly into the position of the licensor. The notion license hence means authorisation.[87]

The construction of the license institute makes it possible to use the license in many different ways depending on the need and the requirements of the parties involved. This makes it an extremely interesting and flexible instrument. Irrespective of the type of actor interested in establishing a license arrangement, if it is a researcher, a research firm or a pharmaceutical company, they can find a construction that suit their aims. For the licensor the license is a means to get paid for the costs he has had in relation with the development of the knowledge and he also wants to receive additional profit on his developed knowledge. The license is for the licensee a means to get access to new knowledge that he can make a commercial profit on.

There is no law specifically governing license agreements, neither in Sweden nor internationally, and there is scarcely any practice developed. This means that ordinary civil law and custom are applicable on these agreements. It is therefore very important that the object of the agreement and each party's obligations are well and clearly defined in the contract to avoid disputes and interpretation problems after the settlement of the agreement.[88]

Most of the agreements we have examined have parties with different nationalities. This makes the agreement international. International agreements are common since the pharmaceutical industry is a global one and many pharmaceuticals are marketed worldwide. In their agreement the parties decide as a rule the law that shall be applicable on their agreement. The chosen law is normally the national law of one of the parties. The law governing intellectual property rights issues is directed of the country in which the agreement is applied. There are also a significant number of international agreements that affect the

[87] Karnell, p 12; Sandgren, 1974, p 121
[88] Karnell, p 28, 54

license agreement and the intellectual property regulation.[89] Such international agreements are for example The Treaty of Rome and TRIPS.[90]

There are also some international standard formulas that have been developed by individuals and organisations that can be used in licensing. Such organisations can be either branch organisations or neutral ones. A standard regulation developed by the former one is ORGALIME's[91] "Model form of Patent License agreement" from 1960, and "Model form of a Know-How Contract" from 1963. Standard formulas developed by a private entity are for example the standard agreements of ICC[92] called Trade Terms and Inco-terms. These refer to international trade customs. If actors consequently and intensively use such principles in licensing some kind of international lex mercatoria for license agreement could develop. Lex mercatoria is a customary law developed by the merchandising actors through usage in contracts. As far as we know no lex mercatoria has been developed regarding license agreements in the pharmaceutical industry. The companies seem to prefer to develop and use their own standard license agreement models.[93]

A standardisation of license agreement does neither seem to have been developed. Every agreement is unique. However its structure and content follows a certain pattern. There are certain clauses that in general are included and their wording is often relatively similar. Such clauses are confidentiality, warranties, indemnities and certain definitions, such as compound and product. Other parts of the agreement where the structure to a certain degree has been standardised are the base for the royalty calculation and the way to handle patent infringements and the prosecution of patents.

5.2 Negotiating a license agreement

The negotiating for a license agreement is often a long procedure. As much as two or three years may have passed from the first contact until the final draft of the agreement is signed. During this procedure several different agreements may have been established between the parties, such as letters of intent, CDAs or MTAs[94]. Before the parties can agree upon the final version of the agreement they have as a rule bandied many different draft between them, as a part of the negotiation.

Even though the parties negotiating often are of a shifting size and may have different experience in negotiation, this does not have to imply that the largest and/or most experienced party has the strongest position when negotiating. The party that owns valuable rights in patents and know-how is in a strong position and he has an extensive possibility to affect the content of the final understanding. This does not have to mean that the size of the company or the experience it possesses may have no significance for how the agreement will turn out.

The first draft of the agreement often becomes the base for subsequent drafts and it pervades the content and formulation of these. It can therefore be of significant importance to create the

[89] Karnell, p 55
[90] The Treaty of Rome is the agreement funding the European Union. In the TRIPS agreement The Berne Convention and The Paris Convention are now incorporated. The Berne Convention of 1886 regulating literary and artistic work and the Paris Convention of 1883 regulating industrial property. Both conventions have been amended several times since they entered into force.
[91] Organisme de Liasion des Industries Mécaniques Européennes
[92] The International Chamber of Commerce
[93] Sandgren, 1974, pp 58
[94] These two shortenings are explained at p 32.

first draft. Of course the content of the agreement has normally been thoroughly negotiated by the parties before the first draft is written. The importance to create the first draft will therefore vary depending on how good the relation between the parties is. This draft may be created by the parties together or by one of the parties. It is usual that it is the licensor that draws up the first draft. Some large pharmaceutical companies seem though to have as their strategy to draw up this draft, independently if they act as a licensee or a licensor. The reason why the larger party often writes the first draft can also be that he has superior legal knowledge and resources.

The content of a draft one party creates is of course studied in detail by the counterpart. To what extent the content of the first draft actually influences the content of the final draft is therefore uncertain. The advantage of writing the first draft is that the structure of it in most cases is maintained, since the first draft establishes the frames of the agreement. The writing party is also often more aware of the legal meaning of the parts he has written and this can be of importance.

5.3 A survey of the studied agreements

We have studied several license agreements between actors in the pharmaceutical industry in order to find out how these actors use the license construction to commercialise knowledge. We will in the following presentation describe how knowledge has been transferred in the agreements we have studied. All parts of the agreements are in our opinion not relevant, or at least less relevant, in order to be able to do this study. We have therefore chosen the clauses we consider reflect this transaction the most. Clauses that not will be examined are for example those treating confidentiality, warranties, re-negotiation, dispute settlement, indemnities, infringement and remuneration matters.

The parts that we find important for this study are those concerning the license construction, ownership of intellectual property and other rights, joint development and other situations when R&D is present, regulatory filings and approvals required for development and commercialisation, aspects regarding the future relation between the parties after the signing of the contract, such as performance and information duty, and termination and consequences of termination. It is these parts that are the heart of the agreement and that give it its specificity. It is also these parts that vary the most between different agreements and around which most the negotiations have revolved.

Besides studying how the commercialisation of knowledge in the pharmaceutical industry has been done in the agreements we have examined, we will also consider different possible ways to perform this commercialisation, used or not used in the agreements. Our purpose is then to analyse and evaluate these different ways to commercialise knowledge, whether found in the agreements or not.

We have had access of totally 15 agreements. Five of these were found on the Internet and the others were supplied to us from different Swedish companies and persons in the pharmaceutical business. Of these 15 agreements 13 are license agreements and it is these 13 that our following study will be mainly based on. We have also had access to an agreement proposal of a nonexclusive license agreement, which we will comment when we consider it interesting and different from other similar agreements. Another source of information has been the answers to the questionnaire.

The two agreements that we have chosen not to use in our study were a distribution agreement and a development agreement. In every agreement that we did examine all figures and percentage rates are excluded and in the agreements achieved from companies, the names of the parties and in some even more information, such as definition of territory, medical field of application, patents and compounds are excluded due to confidentiality concerns. These exclusions do not though affect our study since these parts are not within the scope of our interest.

Among the 13 studied agreements nine of them have parties with different nationality, which means that they are international. In seven of these nine agreements one of the parties is a Swedish pharmaceutical company. Parties originating from the same country can be found in two of the four agreements left, both achieved via the Internet and these two national agreements have American companies as parties. It was not possible to determine whether the two remaining agreements are international or national ones. As a conclusion it can be said that we have not found any difference in how the examined agreements are construed whether they are national or international.

Even though a mutual pattern can be distinguished in the studied license agreements concerning which clauses that are included, none of the agreements is the other alike. They have all their special characteristics and constructions depending on which purpose they are meant to fulfil. Most of the license agreements studied are very long and detailed; especially those with R&D collaboration are comprehensive. Another reason why some agreements are longer and more detailed than others can be that one of the parties is an American entity. In the American and Anglo-Saxon world the tradition is to write longer and more detailed agreements, than in Sweden. Therefore an agreement with a party from the American or Anglo-Saxon part of the world is as a rule more comprehensive than other agreements.

We cannot guarantee that the agreements we have studied give a representative picture of how the license is used to commercialise knowledge in the pharmaceutical industry in broad outline. We have though no reason to believe that these agreements would distinguish themselves from other license agreement in the industry. Our study can however not be seen as a quantitative survey of the license agreements in the pharmaceutical industry, this is neither our purpose. We consider though the number of the examined agreements to be totally satisfactory in order to analyse how the commercialisation of knowledge is performed in this industry. The answers to the questionnaire has also contributed with vital information that could not be obtained by the agreements and also helped to get a better insight into the interests and motives that lies behind the commercialisation activities.

5.4 The object of a license agreement

The absolute basis of a license agreement is its object. The object defines what it is that the licensor gives the licensee a right to use. It therefore forms the subject of the agreement as well as the agreement's outer limits. Together with the license construction, the object defines the rights of the licensee. In general there is a presumption that features the object does not define are not included in the agreement and cannot be demanded by the licensee.

The agreements that we have examined are all created for development and/or commercialisation of a pharmaceutical product. In the pharmaceutical industry it is the patent that is the most important intellectual property but know-how, other types of confidential information and trade secrets are also of significance in order to protect and preserve an

invention. These features are also means by which knowledge can be objectified and thus transferred between the actors in the industry to be further developed and commercialised. Therefore it is not astonishing that ten of the studied agreements have both patents and know-how as their object. When we use know-how here we include in this notion information, data, knowledge and inventions relevant for a compound or alike.

These ten agreements are both exclusive joint development licenses and exclusive licenses, which are worldwide or restricted to certain areas. It is only in one exclusive agreement the object is restricted to patents, which in this case are jointly owned by the parties. This agreement has as its licensor a group of inventors. Two other agreements that have licensors who are somehow linked with the academia are nonexclusive and these two also have only patents as their license object. It might be so that an invention, which has its source in the academia, is in a very early stage of development and has thus none or very little developed know-how surrounding and connected with it, which results in that there is no relevant know-how to include in the licensed object. Another reason why the agreements, which have a licensor that is connected with the academia, only have patents as their object might be that these are more reluctant to share their know-how with others. Researchers within the academia do not perform research with the main purpose to develop new pharmaceuticals. Their information and data connected to a patent is perhaps neither that useful for a pharmaceutical company, since it is not focused on drug development. This can also be a probable reason why no know-how is included in the object.

We have seen that a license agreement can be divided in two parts, which one relates to R&D and the other to commercialisation. This is the case in three of our examined agreements, which all include joint development. When the parties have chosen to divide the license like this it seems to be a practice to have two object definitions as well. A result of the existence of two object definitions is that this part of the agreement is long and detailed, since both objects contain patents and know-how.

To have two separate objects must be seen as a good solution since an R&D license and a commercialisation license have different purposes and conditions. Regardless of this divergence there is though a tight connection between the R&D license and the commercialisation license. It is after all the results of the R&D that will be commercialised. The consequence of this tight lien is that the object is defined almost the same in the two licenses.

A license agreement that is not divided in two parts has naturally only one object. The rest of the exclusive license agreements are construed like this and they have all, except one, both patents and know-how included in the single object. The part of the agreements in which the object is defined is consequently shorter than in the agreements with two objects, however not meaning that they are less favourable and clear.

Regardless whether the agreement has one or two objects it is however the definition of know-how that demands most specifications. It is easy to define a patent since it is its number that is the relevant information, but the definition of know-how is much more delicate. It is important that the parties are clear of what the object includes regarding know-how since it is only the defined features that are included and that shall be transferred and utilised. An agreement that does not include know-how in its object is thus much more restricted than an agreement that has know-how as its object. The object decides thus what shall be the basis for activities performed under the agreement.

An object in a license agreement with one object for both patents and know-how can be construed like this:

> "Patents owned by the Licensor, patents owned by a third party and which are licensed to the Licensor. Patents owned by or licensed to the Licensor during the term of the agreement may also be included if elected by the Licensee. All inventions, concepts, processes, information, data, biological materials, know-how and the like now and hereafter owned by the Licensor, that are used or useful in the use, manufacture or sale of the Licensed Products."

It also seems to be a tendency that improvements of the licensor are included automatically in the object of the agreement. This is the case in six of the studied agreements; all of these are exclusive with and without joint development and have as their licensees a pharmaceutical company. To include improvements developed by the licensor automatically in the object can be seen as a practical and easy means to make relevant improvements a part of the license if the parties have such a desire. The opposite situation, when a licensor shall have a right to the improvements of the licensee is not so frequent in our agreements. Actually it is only in two of them that this is mentioned in the object and in both cases the licensor is a pharmaceutical company. From the licensor's point of view it should be of great interest to have access to improvements done by the licensee if the licensor performs activities related to the licensed object.

As we have seen the object of a license agreement can thus be very detailed or only written in brief words. The studied agreements in which the parties are collaborating in R&D and in most of the exclusive licenses the object are often formulated in detail. Concerning the nonexclusive licenses the situation is totally the opposite. When the object includes only patents no detailed explanations have to be done, since the most important for the licensee is a reference to the number of the relevant patent(s). To be concrete and detailed is however as a rule to recommend since disputes then more easily can be avoided and the parties know for what purpose the agreement actually is entered into. It is though natural that an object that does not consist only of patents but also of know-how is more delicate and demands more regulations and explanations. The advice is anyhow to spend much time on the formulation of the object of a license agreement since the object is the basis for the whole agreement.

5.5 Information duty - A pervading characteristic of the agreements

Some kind of an information duty between the licensor and the licensee can be found in almost every part of a license agreement and it appears in a number of different shapes. In a license relation it is important for the parties to know if the other party is acting in the way that the agreement anticipates and as was agreed upon. To achieve information regularly is vital for the parties in order to be able to affect a party's behaviour before its actions causes any damage to the other party. Such damages can for example have negative effects on the licensor's proprietary rights related to the agreement, which in this study are patents, on the economic situation of either party and they can of course result in considerable badwill.

For an actor commercialising knowledge and technology in order to launch a new product in the pharmaceutical industry the information duty has several means. Since the development and commercialisation activities are risky, expensive and strictly controlled by the authorities during the development phases, the parties are anxious to insert an information duty regarding these activities in the license agreement. Sometimes it happens that the textual formulation of the information duty regarding research has been made too wide, meaning that almost all kind

of research activities, even ideas and thoughts are included in the reporting obligation. Since a license regarding research normally has a certain determined direction, it is then not realistic for the parties to follow a wide over-all-covering reporting obligation as long as the actual intentions with the information duty are met up to.

When the end product then has been launched in the market the information duty is a means for the parties to obtain knowledge in how the product is managing in the market and how the market is functioning during the term of a license agreement. It seems to be quite common that information about market activities and incentives are not fulfilled despite an agreement that states the contrary. This is often due to that the parties do not want to share their knowledge and strategies with each other.

An example of when the information duty may be ignored can be in a cross-license agreement. Such an agreement can state that the parties shall exchange two substances in order to sell a specific pharmaceutical under different brands. In this agreement the parties are both licensees and licensors. The parties can then agree upon that the party acting as a licensee shall have an obligation to inform the party acting as a licensor about the marketing activities of the product. The licensor has an interest of this because he will be marketing the same product but under another brand. Despite this agreement-stated obligation the tendency is that the information transfer will be almost non-existent.

Normally every licensing of a larger size in a pharmaceutical company has its specific project groups. It is these groups that handle the licensing and most frequently they will notice if any requested information has not been received. In general it can be said that it is relatively difficult to control if the information duty is met. To write down concretely the requirements of the parties regarding the information duty so that the results can be estimated, can though be a means to obtain better control of the duty. Although written down it is of course very difficult to know when the counterpart is holding back internal information of for example appropriate technique and marketing strategies. But in the long run such withholding of important information will normally be discovered.

Despite the possibilities to get off the information duty, an obligation to report specific information seems to be considered important by the pharmaceutical actors. They have no desire to intentionally and spitefully ignore an agreed contractual obligation. Even if the information duty cannot be strictly controlled it has thus a preventive effect on the parties.

Each one of the agreements that we have studied has a specific purpose and is created in order to meet this purpose. The purpose is ascertained in the object of the agreement as well as in the specific license construction. Therefore the information duty is shifting in the 13 studied agreements. How extensive this information duty is depends on how the license is construed, whether it is exclusive, nonexclusive or sole. In an exclusive agreement where the parties are performing joint development there is normally a tight relation between the parties. As a result there is quite an extensive information duty between them, since they have an interest in how both development and further commercialisation activities proceed. Although no R&D cooperation exists, an exclusive or a sole license agreement however has many information duty regulations. Even in the nonexclusive license agreements a more or less extensive information duty can be found.[95]

[95] This conclusion is based on the agreements that we have studied and shall not be seen as a strict and well established pattern for other license agreements in the pharmaceutical industry or other sectors using such agreements.

In general it can be said that the studied agreements showed mutual characteristics as regards what kind of activities that require information duty by either or both parties. It is however important to point out that these activities cannot be found gathered in the same way in all the agreements. Depending on how the license is construed, as a result of its desired purpose, different kinds of activities requiring information duty are picked out and put together in every specific agreement. In some agreements we found an article called exchange of information but such an article is not exhaustive concerning the information duty in the specific license agreement. All the studied agreements showed despite some grand similarities their own system to order the articles.

The examined 13 agreements are in general signed in the early stage, the pre-market stage, of the development process of a pharmaceutical product. Therefore these agreements have quite an extensive information duty concerning R&D, whether performed in collaboration or not. But there is of course even other contractual activities for which reporting are required. Since the information duty always is linked with other activities under the license agreement it is in general not appropriate to separate it. Therefore the information duty will be discussed in connection with the contractual activities under which relevant and interesting information duty, regarding commercialisation and transfer of knowledge, can be found.

5.6 Different variables of the license

The granting of the license is the most important part of the license agreement. It is the heart of the license agreement and of the commercialisation. It is here the rights of the licensee are determined and the extent of how he can operate in different activities is defined. How the license is construed and how extensive it is greatly influences other clauses of the agreement, as we shall se later on. The clauses regulating intellectual property and improvements are probably more affected than others because of their close connection with the rights the licensee has obtained though the license. But also the consequences of termination of the agreement, as will be shown, differ depending on how the license is construed.

The licenses granted in the agreements we have studied varied a lot. Though they do have similarities, none of them is the other alike. This is because each license is granted with a purpose specific for the situation and of the parties entering the agreement. There are four components of a granted license that can vary in the following different ways:

1. The license can be exclusive, nonexclusive or co-exclusive/semi-exclusive[96]. If the license is *exclusive* the licensor has an obligation not to give other licenses in the area of the licensee and to stay out of the exclusive territory himself. If it is *nonexclusive* the licensor has the right to grant additional licenses to other persons/companies and is free to compete, for example manufacture and sell the product, in the territory without restriction during the term of the agreement. The *sole* license means that the licensor is not allowed to grant more licenses in the licensee's area, but he is free to compete with the licensee in this area himself. If the agreement does not mention if the license is nonexclusive, sole or exclusive the license is assumed to be nonexclusive because this type of license limits the rights of the licensor the least.[97]
2. The geographical field of use of the license can vary. The license can be worldwide or almost worldwide (excluding a few countries) or just concern certain countries or areas. If

[96] Both terms have been used in our examined agreements, both meaning that the license is sole.
[97] Singleton, Exclusive, sole and non-exclusive license

the granted license does not have a worldwide application, this means that the licensor is free to use the granted rights as he prefers in the countries not included in the agreement.

3. The medical field of use of the license can differ a lot. It can include all possible applications of a substance, a specific disease/condition or a certain application. The licensor decides in what field of application the licensee may use the rights and if the granted technology has other fields of application that is not included in the license, the use of the rights for such applications can be granted to others or used by the licensor himself.
4. What the licensee has the right to do with the rights granted, what activities he is entitled to perform, can vary. In the most extensive licenses the licensee has the right to develop, use, make, offer to sale, sell, manufacture, market, export and import the compound, technology or product that is included in the granted license. The parties can though choose which of these components to be inserted so that the purpose of the specific agreement is met.

By adjusting these four variables the parties can construe many different types of licenses with an extremely high divergence. Different types of licenses are used in the agreements that we have studied affecting the scope of freedom of action for the parties involved.

5.7 Regulations regarding R&D

5.7.1 Joint development licenses

In four of the 13 license agreements we have studied there is a joint development, with a well-regulated development program. Such agreements that constitute research programs are often called collaboration agreements. The simpler forms of collaboration agreements, where one party undertakes a long-term research program and the other party uses the results of this to develop and market the intended product, are often done between universities or smaller companies and pharmaceutical companies. In the more complex forms of collaboration agreements established between pharmaceutical companies both parties undertake research programs and share the results and use these as agreed.[98]

In three of these four agreements, which do include a collaboration regarding research, the license is divided in two parts, one concerning the development and the other concerning the commercialisation. The license is in all the three cases restricted to the performance of the joint development. The development license is in the agreements sole, except one that is nonexclusive. In the agreement it is nonexclusive the parties may not grant any additional licenses to a third parties, during the term of the research program, that has the same subject as the research the parties will perform together. This nonexclusive license has hence the same implication during the research program as the two sole ones. It is only the two parties of the agreement that will have the right to use the technology specified in the agreement in order to carry on research.

In one of the three cases where the license is divided in two parts both parties possess technology that will be used in the joint R&D performed by the parties. In this agreement it is difficult to categorise the parties as licensor and licensee, since the agreement is a cross-license regarding the R&D cooperation. We have anyway chosen to name the parties licensor and licensee. The party that we call licensor is the one that obtains the ownership in the joint

[98] Ranson, Research agreements: The Devil in the Detail

developed property. It is also the party that we feel is the stronger of the two. The parties are two pharmaceutical companies active in different parts of the world. The developments emanating from the joint development will be commercialised by both parties but in different territories. In this case the joint development is a means to unite and combine the technologies and the know-how both parties possess and develop these to something better. This is of course a good solution when both parties are pharmaceutical companies active in the same medical area but in different parts of the world and both possess something that is of use for the other.

In the two other agreements it is one of the parties (the licensor) that possess the technology that will be developed, but it is still both parties that will perform the development. In these cases the licensor is a small pharmaceutical or research company and the licensee is a large multinational pharmaceutical company. It is, in these two agreements, the licensee that later will perform the commercialisation the result of the joint development, at least the major part of it.[99] One of these two development licenses read as follows:

> "Mutual Research Licenses. (a) Licensor hereby grants Licensee, during the term of the Research Program, a co-exclusive (solely with Licensor), paid-up, world-wide right and license under the Licensor Licensed Technology and Licensor Collaboration Technology …. to conduct the Research Program and to make and use Collaboration Compounds and Covered Products in connection with the Research Program, each in accordance with the terms of the Agreement.
> (b) Licensee hereby grants Licensor, during the term of the Research Program, a co-exclusive (solely with Licensee), paid-up, world-wide right and license under the Licensee Collaboration Technology to conduct the Research Program in accordance with the terms of the Agreement."[100]

It is the licensee that has the commercialisation ability in both these agreements, but since the licensor has particular expertise in the relevant field of research this knowledge is used in the joint development. In both these cases the license agreement is established in an early stage of the development. Given that the licensor is a small company with no or limited commercialisation capability it is important for him to find a strong partner that can commercialise the technology on a worldwide basis. A license agreement where a collaboration research is included is then a way for him to continue the development, having the future of the technology secured, and to get remunerated for it. For the licensee the interest lies in the knowledge the licensor possesses. If the knowledge of the licensee was not so vital for the project the licensee could more easily take care of the entire development by his own. If some sort of assistance is needed from the licensor, though not so much that it is necessary for the licensor to have the licensee as a joint developer, such assistance could be included in the agreement. Such regulations are found in other agreements. The licensee then has a certain right to consult the licensor. This possibility to consult the licensor is as a rule limited in time and it may be for free up to a certain used hours, but then gets payable. This consultant possibility may also be optional.

In the remaining agreement that contains a collaboration regarding research the license is not divided in a development and a commercialisation part. In this case it is the licensor that possesses the technology that will be further developed by the parties together. The license

[99] In one agreement the commercialisation license is sole in one country. In the other the commercialisation license is exclusive only regarding the field of application defined in the agreement and it is nonexclusive regarding the result of the joint development used in other application.
[100] The excluded part under (a) relates to a sublicense that also was granted. Words with capital letters have a certain definition in the agreement.

granted to the licensee is exclusive. It is mainly the licensee that will perform the R&D, but a certain number of persons working for the licensor will also work with the development. The licensee will though pay the licensor for all the expenses he has as a result of the development he performs related to the agreement. As in the two agreements mentioned above the licensor is in this agreement a company with a specific knowledge in a certain medical field and the licensee is a larger company with expertise in development and commercial exploitation.

In another agreement there is no joint development though there is a development program and a development committee. The object of these two are thus only to control that the licensee execute his obligations as set forth in the agreement. Such means of control will be further discussed under section 5.11.

5.7.2 The research program and its characteristics

In the four agreements in which there is a joint development this cooperation is performed in accordance with a development or research program established by a development or research committee. In this committee representatives from both parties can be found. Whether the parties are large pharmaceutical companies or a small pharmaceutical or research company and a large company the construction and composition of the joint programs and committees are quite the same. The committee and the program can be seen as creations to more easily handle and manage the collaboration in R&D under the agreements.

The following quotations show how the joint committee and program can be presented in a license agreement:

> "Collaborative research … they will conduct a Research Program on a collaborative basis, … The specific scope of the Research Program shall be set fourth in the Research Plan established by the Joint Research Committee …."

> "The Parties shall establish a Joint Committee which shall comprise three representatives designated by each party. The Joint Development Committee shall be responsible for overseeing and directing the Research Program and overseeing the Licensee's development and commercialisation efforts"

The committee shall develop a strategy or plan for the R&D program. This strategy or plan is shifting depending on what the parties want to attain with it. The plan directs the work of the parties under the program and the committee's mission is to see to that the program is functioning as predicted. All the four agreements have detailed descriptions of the responsibilities and obligations of the committee but two of the agreements are even more detailed. The committee shall meet within regularly intervals. In the four collaboration agreements that we have studied these meetings can occur between once every calendar quarter and twice a year depending on the agreement. The parties have however a possibility to meet more frequently if needed. Such meetings are important to control how the collaboration and the transfer of knowledge and technology are managing.

The joint R&D activities are the source from which new knowledge and improvements will arise. It is thus the license agreement that is the instrument through which such R&D results will be transferred between the parties. Since the parties are cooperating in R&D it is very important that they keep each other up to date regarding how the R&D work proceeds and which measures that will be taken. One of the purposes with the creation of a development or research committee is therefore to facilitate the exchange of information and reports of the

parties' respective activities during the R&D cooperation, under the development or research program.

The information duty during the R&D cooperation is thus first of all related to the exchange of reports of their respective activities under the joint program. However it is also a means through which other types of information that a party possesses and which can be of interest for the other party can be received. Each party has normally an obligation to keep records and books concerning the progress and status of the R&D program. Such records may consist of different studies, reports and documents over for example pre-clinical studies, clinical studies or over other performed research. This kind of information shall thus as a rule be disclosed to each party. An example of a clause in which information and records are dealt with can be as follows:

> "Licensee and Licensor will make available and disclose to each other all Information resulting from or arising out of the work conducted under the Research Program during the Research Term. All discoveries or inventions made by either Party resulting from or arising out of the research Program will be promptly disclosed to the other, with significant discoveries or advances being communicated as soon as practical after such information is obtained or its significance is appreciated. The parties will exchange at least monthly verbal or written reports in English presenting a meaningful summary of research done under this agreement. In addition to any presentations made through the JRC [Joint Research Committee], each party will make regular presentations to the other of its research under this Agreement, and additionally on an informal basis, to inform the other Party of the work done under this Agreement."

The information duty can be more or less detailed. Whether detailed or not the information duty regarding R&D collaboration seems to be an important factor for the parties. Through this duty they can be aware of each other's activities and eventual progresses or improvements, which is one of the most important elements in R&D cooperation.

To prevent disputes and uncertainty of how the information duty shall be interpreted the parties should in detail and exact words formulate and describe what they intend with and expect of this duty. If it in the agreements is clear definitions of all the components in the reporting obligation agreed upon there will be no or very few opinion divergences and the relation between the parties will be positive and trustful. Even if a license agreement is not terminated because of incompliance with the information duty, such an action by the obliged party will usually deteriorate the relation between the parties. The parties should therefore during the negotiations, that take place prior to the final draft is signed, thoroughly discuss and write down how they want to regulate the information duty. The more they have knowledge about and can do prognoses of how the other party will act and even more important about how the courts and other authorities will look at and deal with information duty issues the better are the possibilities to formulate a suitable and useful information duty clause.

5.7.3 Modification and amendments of the research program

The joint program often has to be regularly modified or amended after a certain period during the term of the license agreement along with the proceeding of the R&D. Such modifications are frequently necessary in order to improve and to fulfil the purposes with the R&D work. When a modification is done the parties normally have to be informed by the committee. Any decision-makings within the committee seem according to the studied agreements to require unanimity. If the parties cannot reach unanimity the matter is referred to some kind of

member of a senior management or another type of higher instance at the parties'. In one agreement that is partly exclusive and sole and in which the parties are a large pharmaceutical and a small research company it is however the large party, the licensee, that shall have the final decision, but the other party's, the licensor's, consent is required if it concerns an activity under his responsibility. In another similar agreement the licensee is entitled to make decisions on product definition and selection, toxicity and safety, clinical research and marketing and sales.

In both the exemplified agreements it is the licensor that has contributed with the knowledge and technology the development work will be based on. In the agreement that is partly sole and exclusive both parties are equally performing the joint development. The licensee is as said a large pharmaceutical company with a lot of experience in R&D and commercialisation of pharmaceutical products. The size and competence of the licensee is undoubtedly the reason why the licensee has the final decision regarding the joint program. But the licensor has seen to that his consent is required under his responsibility sphere. This arrangement is thus most advantageous for the licensee but the licensor has also a good position regarding such activities that are of his special interest. The agreement has created a solution that both parties should be satisfied with in general.

In the other agreement the situation is somehow different. The parties are cooperating in R&D to some extent but it is the licensee that is performing most of the R&D work. Actually the licensor, a company active in a certain field, is not so involved in this work since the development license is exclusive for the licensee, a large multinational company. Therefore the fact that the licensee has the decision right concerning activities such as product definition and selection, toxicity and safety, clinical research and marketing and sales is no accidental occurrence. The licensee is the major performer of R&D and should though have this right. However this is not so advantageous for the licensor who will not have any real influence and control over such decisions, which largely will affect the development and commercialisation of the licensed knowledge and technology. In this agreement is thus the large party that has the control over the R&D and the commercialisation under the license.

A development or research program and committee should be created in favour of both parties and therefore the fairest means to make a decision is with unanimity. However such a system will probably be quite difficult to practice in reality at least in situations when the parties have different opinions and it is unrealistic to think that they in most cases are of the same opinion. A solution could be that the party that will be affected the most by a suggestion should have a veto right, but only if the proposal is very negative and disadvantageous for the non-suggesting party. If an offer to the contrary is advantageous and positive for the purpose of the committee and the program it should be accepted if a majority in the committee is in favour of it. The problem is however who will decide which proposals shall be regarded as disadvantageous or advantageous. To have a regulation that has to be individually interpreted each time a proposal is given can hence be problematic. A positive aspect of unanimity is that if it is used the parties have to do their best to find a solution that both are satisfied with. But the system, as it usually seems to be today, with the reference to a higher instance or alike makes the unanimity instrument quite hollow. On the other hand if a party is given the decision right the other may consider itself put aside and may have no interest in continuing the collaboration and might consider taking actions against the deciding party. It is of course easier to hypothetically suggest how to handle the accomplishment of any suggested amendments, than it is in reality.

5.7.4 Ownership in intellectual property developed during the performance of joint development

In three of the four agreements that withhold a collaboration research program the parties will own the results of the collaboration jointly in an undivided interest. But these agreements also state that the developing party shall exclusively own any technology or information developed by either party independently from the other party. All these three agreements are very alike in their regulation of this question. Here follows an example of such a regulation:

> "Each party shall retain the sole title to any technology, know-how, inventions, concepts, processes and the like (whether or not patentable) which it develops solely … Each party shall own a fifty percent (50%) undivided interest in all technology, know-how, inventions, concepts, processes and the like (whether or not patentable) made, conceived, reduced to practice or generated jointly in connection with the Research Program…."

In the other agreement it is the licensor that will own the entire right to the intellectual property developed by the parties in collaboration. The licensee therefore assigns to the licensor his entire interest in any information created, developed or discovered under the research program. The solution found in three of the agreements seem to be the most logical when parties perform development together, this solution also appear to be the most common one. Practice should imply that it is the party that pays for the development or contribute with knowledge, who shall own the rights to the intellectual property.

For the licensee the question of ownership is not that important. The possibility to use the rights is the same irrespective of whether the licensee owns the rights or has an exclusive right to use the rights. This is very important to point out. The question of ownership may though be of more importance for the protection of the rights, for example during an eventual infringement, or at the termination of the agreement. It is advisable if the party having the best possibilities to protect, to maintain and to develop the rights is the one who will obtain ownership. Irrespective whichever of the parties that owns the rights to the intellectual property the most important is that the communication between the parties is good and frequent. The owner of patents must harmonise the actions of maintenance and prosecution with the party that is responsible for the marketing of products.

5.7.5 A research program's term, termination and consequences of such termination

Cooperation in R&D is normally restricted in time. All the four collaboration agreements have their own term. In two agreements, where the R&D cooperation is performed trough a sole license the term is on a four-year basis respective until the last element in the joint research has expired. In the nonexclusive one the term is at least three years and in the fourth sole license the term is hidden due to confidential matters.

Either or both parties can normally cause the termination of a research program. The research program and collaboration can for example be terminated upon a material breach, if there is no adequate progress, large changes in the ownership of a party's business, if there is no left interest to continue the collaboration in R&D and in case of bankruptcy or insolvency. In the four agreements with joint development the licensee has the sole right to terminate the research program and collaboration in two agreements and in one this right is shared with the licensor. Only in one agreement such a termination right is solely in the hands of the licensor.

The reason why the right is solely the licensor's is probably that it is an innovative asset of the licensee that is the object for the R&D collaboration. A lot of input of knowledge and technique is done by the licensor in order to improve the licensee's innovative asset. It seems to be an important kind of input that the licensor contributes with and that the licensee shall have access to. Therefore the licensor has seen to that the licensee cannot terminate in his sole discretion, since such termination could cause the licensor damages and result in his input efforts becoming meaningless for him. It is thus only if the licensor considers the research program not progressing as expected that determines whether this program shall continue or not.

An obligation to inform the other party if one of the parties has an intention to terminate the agreement is a similarity that can be found in all the four agreements. Regarding termination by any cause the announcement to the non-terminating party that shall be delivered, before the termination will be effective, can vary between 30-120 days. If the termination is based on a material default the receiving party of such notice then normally has a specified time within which he can cure the default. Sometimes there are though no possibilities to cure because the facts, which the termination warning is based on, are incurable. An example of an incurable fact is bankruptcy or insolvency.

In two of the four agreements the research program cannot be terminated before three years have passed from the effective date of the agreement. The licensee has the termination right in one of them and the licensor in the other. The agreement in which the licensee has the termination right, the licensee is a large multinational company and the license is exclusive. It is however required that the research program has not changed during the notice period. The result of a termination of the research program will be that the licensee has no right to sell products or services in the licensed territory during a five-year period. The termination of the joint development will thus affect the licensee's commercialisation license and he will have no further such rights. The position of the licensor in this relation is then quite strong even if he is a company of a smaller size.

The other agreement is very different from the other three since it is the only one in which the licensor is the party that solely can terminate it. The three-year requisite is the same as in the agreement above and the consequence of the termination of the licensor is that the ownership and rights of the joint technology shall be transferred to the licensor entirely and worldwide. The licensor has a very strong position while the licensee is granted no rights at all even if he is active together with the licensor in the joint development work. They are both pharmaceutical companies, but active in different parts of the world and both are contributing with knowledge and technology to the research program. The licensee is thus put in a disadvantageous situation especially since the licensor can use the joint technology worldwide, meaning even in the field of the licensee, after a termination of the research program. This agreement is actually a cross-license agreement and this is thus one reason that makes it different from the others.

The two remaining license agreements are one sole and partly exclusive and one exclusive. They are very different in how their licenses regarding R&D collaboration are construed. The former one of them is very detailed and complicated. The licensee, a large multinational company, is given a special right to select which compounds and products that shall be further developed. He can choose to abandon such selected compounds, which will result in that the licensor, a small research firm, shall be granted a nonexclusive license under the improvements and findings the licensee has done during the development. This nonexclusive

license shall give the licensor a right to use such rights of the licensee in his development and commercialisation of the compound in the territory, meaning almost worldwide. Additionally the licensor has a right to sublicense this granted rights. The licensee can also choose to discontinue all of the compounds and then the agreement will terminate in whole, but the licensor will still have the same license right as just mentioned in the other case. This is a good thing for the licensor who otherwise could loose important commercialisation possibilities in the area where he is active.

In the other a termination of the research program of either the licensor or the licensee will not affect the rest of the agreement and both parties will have the right to sublicense the licensor's and the joint technology outside the licensed territory. The licensee is a large multinational company and the licensor an intermediary company. Both these agreements have a similarity in that in case of a termination of the research program the licensee shall transfer important and necessary development information and other material to the licensor. This is very important since the licensor otherwise should not have the needed knowledge, technology and information in an eventual sublicense situation.

It is interesting that in the former agreement the research program seem to be so important that the whole agreement shall not continue if the program is terminated. It is also the licensee, the large party, who is deciding the destiny of the program since he is the party having the termination right. In the latter one the termination of the program has not such an influence of the agreement even if the parties on a large scale are performing joint development. This agreement is however giving the licensee the major rights to terminate since the licensor's right is restricted to only one circumstance. The licensee, even here the larger party, has thus the strongest position regarding termination possibilities of the research program.

Since both parties are active in a development program the optimal situation seems to be that each of them should have a right to terminate the program. To give the termination ability solely to the counterpart is normally a huge decrease regarding the control position of the renouncing party. But if there is no options the renouncing party should see to that he will at least have something in return, for example a license to the results relating to the joint development that the non-terminating party does not posses by his own or does not have a right to use without a permission of the other party. However the parties must have a right to construe their license agreement as they want and in accordance with their purposes and whether the termination rights shall belong to both or to a single party has to be in the sole discretion of the licensor and the licensee.

5.7.6 Non-joint development license agreements with information obligations regarding R&D activities and their progress

Even if the parties do not have a license regarding joint development it is relatively common to find regulations for R&D activities in a license agreement. Usually in such license agreements it is the licensee who has taken over the development work from the licensor. The licensor is therefore obliged to transfer to the licensee all the relevant know-how and other data, documents and other information necessary for the licensee to perform his R&D work under the license agreement.

The licensor who has transferred his R&D activities in a specific pharmaceutical area to another actor should normally have an interest in receiving regularly information about how

the R&D work is proceeding and about the results arising from it. Despite all the licensor is still the owner of the licensed knowledge and technology. The studied agreements showed that the licensor takes such an interest in the development activities of the licensee whether the license agreement is exclusive and worldwide, exclusive but restricted to a certain or several countries or even nonexclusive. To abandon all possibilities to control and overview the development could be a disadvantageous for the licensor. Even if the licensor has no direct desire to be involved in the further development and/or commercialisation he should at least to some extent require the licensee to report how he is handling the R&D work of licensed invention. Actually it is the licensors who are somehow linked with the academia that should look after their interests in information reporting from the licensee more actively than they usually do today. Besides the four agreements with collaboration licenses there are eight licenses in which R&D activities can be found. Only one of them is not exclusive.

As already mentioned the licensee has taken over any eventual R&D work in the agreements in which such work is not done in collaboration between the parties. Consequently it is as a rule the licensee who shall inform the licensor of the R&D work, but there can be divergences. Such reporting obligations for the licensee can be found in four agreements of which one is nonexclusive. In one exclusive license of these four agreements some sort of information duty also lies on the licensor. The information duty is either put separately or in connection with the filings of regulatory approvals. Facts regarding regulatory filings for different approvals that are of interest for commercialisation and transfer of knowledge will be discussed later under section 5.12.

In the agreements where the licensee has a reporting obligation of R&D work it is primarily the licensee's progress of the development and of the licensed knowledge and technology that the licensor wants to receive information about. In the studied agreements it is no difference regarding this progress reporting whether the licensee is a large multinational company or a smaller more research-intensive company. The licensor has transferred knowledge and technology to the licensee and can thus see to that he has some control over the licensee if there is such an interest. Here is an example of an R&D activity information duty from a nonexclusive agreement:

> "PROGRESS REPORT—On or before August 25 of each year, beginning August 25, 1998, curing the term of the agreement, Licensee shall make a written annual report to Licensor covering the preceding year ending July 31, regarding the progress of the Licensee toward commercial use of the Invention(s) and Licensed Patent(s). Such reports shall include, as a minimum, information sufficient to enable Licensor to satisfy reporting requirements of the U.S. Government and for Licensor to ascertain progress by Licensee toward commercializing the Invention(s) and Licensed Patent(s)."

An agreement, in which the licensor has an information obligation of the development, is quite special from the others. The parties have, in the agreement, established a development program and committee although these two features do not found a joint development. The licensor and licensee have an information duty to each other regarding relevant information, such as know-how, techniques and data from trials and other research activities, which is relevant for the licensed object. This information duty for both parties also includes reporting of improvements and inventions done during the agreement.

Since the exclusive license in this agreement is restricted to certain countries and not worldwide the licensor is still active regarding R&D work in the field the licensee is excluded from. Such R&D work, its results, connected information and improvements can be of

importance for the licensee if relevant for the licensed knowledge and technology. The licensor is also to some extent active in the licensee's exclusive territory concerning certain required non-clinical studies and these activities requires a reporting obligation to the licensee. Therefore an establishment of a development committee can be seen as a means for both parties to achieve information of each other's R&D activities, both in the licensed territory and outside of it. The transfer of information shall normally take place in the committee. Even if the licensor has some reporting obligations the main mission of this committee is to facilitate and coordinate the exchange of information from the licensee to the licensor.

All these commented agreements thus include more or less R&D activities and the information duty for the parties is very detailed in some and in others almost not mentioned at all. The pervading characteristic seems however to be that the licensor shall be at least somehow informed of the progress and status of the development work the licensee is performing. In return the licensor normally has to disclose and transfer all the relevant information relating to the licensed invention to the licensee so that he can perform his R&D work as the agreement states.

In one agreement the parties have established a joint team in order to facilitate the transfer of licensed know-how, technique and patents from the licensor to the licensee. In this case the licensor is a large multinational company and such an arrangement should be of interest of the licensee. Both the licensor and the licensee are experienced in development and commercialisation of pharmaceutical products. The parties are thus probably well aware of that the administration of transfer of relevant information agreed upon can in some cases be problematic to perform, and even ignored. Then to handle such information transfer through a joint team can be a good option for the parties. A joint team will consist of representatives from the licensor and the licensee. This is a good thing for the licensee because as he is represented in the team he will meet the licensor regularly. The licensee has thus a larger ability to put some pressure on the licensor so that he will realise the transfer he is obliged to do in time and to an appropriate extent.

Maybe a joint committee or team construction is something that more frequently could be used in practice by the actors in the pharmaceutical industry when commercialising and transferring their knowledge techniques. Since both parties are represented it will probably be more effective to remind a party of its information duty regarding R&D activities and progress during such meetings face to face than through a written announcement with the same content.

In one of the nonexclusive license agreements we could not find any actual information duty concerning R&D work. Actually this agreement is more focused on and constructed for commercialisation activities. It seems like the licensor in this relation is taking care of the development and the licensee is instead a channel trough which the licensor can achieve better commercialisation areas and results. The licensor is a non-profit-corporation and has thus no special interest in commercialisation and large profits. The main interest of the licensor is instead to earn some money so he can afford further R&D activities and start up new interesting R&D projects. A licensee willing to take care of the commercialisation of the development results is what the licensor is searching for, since the licensor has no such resources himself. Therefore it is not astonishing that there is no information duty for the licensee to the licensor since the R&D issues are not the interesting element in his relation with the licensee.

It has to be noticed that in all the studied license agreements whether exclusive or nonexclusive the licensor always, without any exemptions, has to transfer information and technical assistance relating to the licensed invention. Such information and assistance, which can be both background knowledge and experience, in other words know-how, shall normally be transferred to the extent needed for the licensee so he can use and apply the licensed knowledge and technology. In general such disclosed information is regarded as confidential between the parties. The transfer of such knowledge and information is required if any success in commercialisation shall be achieved.

5.8 Licenses relating to commercialisation activities

5.8.1 Exclusive, sole or nonexclusive licenses

All the agreements we have studied include commercialisation, meaning that they include a right to sell a product in the market. The extent of this right does though vary a lot. Two of the licenses are nonexclusive, ten are exclusive and one is partly exclusive and semi-exclusive.

In one of the ten agreement mentioned above as exclusive there is a mutual nonexclusive license regarding the use of the licensed rights in other field of applications than specified in the agreement. This agreement also contains a joint development. In these cases it can of course be in the interest of the party not commercialising the results of the joint development, in this agreement the licensor, to maintain a right to use the results from the development in applications not regulated in the agreement. One of the agreements that are partly sole and exclusive has a similar regulation, but the license regarding the field of application outside the field specified in the agreement is in this case, as the main license, partly exclusive and sole. Also in this agreement there is a joint development.

In two other agreements among the ten exclusives the licensor has an option for a license. In one case it is an option of co-marketing, which the licensee can choose to give the licensor one year before the licensee's obligation to pay royalty in each country expires. This obligation to pay royalty terminates in each country at the later of the expiration of the licensor's patent protection in a country or 12 years from the first commercial sale in such a country. In this agreement the licensee may also grant the licensor a sole license regarding manufacturing. The choice to activate the option is in this agreement totally in the decision of the licensee. It is hence the licensee, who decides if he wants to give the licensor the option. The licensor is though free to decide not to exercise the option if this is what he wants.

The other exclusive license containing an option gives the licensor the opportunity after the licensee has completed the phase two clinical trials to decide to exercise the option that gives him the exclusive right to develop and commercialise one of the two formulations of the product. If the licensor decides to exercise the option the licensee will grant an exclusive worldwide license regarding his improvements to the licensor. The licensee will continuously have the exclusive right of the other formulation. In this agreement both parties are pharmaceutical companies, the licensor with a broad field of business and the licensee specialised in the area the license concerns. The decision whether to exercise the option of not is hence totally the licensor's.

One of the agreements with an exclusive license is a real option agreement. The licensor will in this case continue his development until a certain in the agreement defined point is reached,

in this case clinical trials phase two, and the licensee shall then decide whether to use the option to accept the license or not. His decision depends on the results of the trials the licensor will perform. Since the licensee pays a certain signing fee, the licensor receives contribution to the costs that will be connected with the development he will complete. Option agreements are frequently used to secure access to technologies in a very competitive field or to buy time. In our case the licensor is a small intermediary firm and the licensee is a large multinational pharmaceutical company. The licensor is in need of a global partner and the licensee is in need of new knowledge. Since the licensor hopefully gets a good price for the option, this can be seen as a compensation for some parts of his expenditures related to the development. Given that the licensee probably will exercise the option, the licensor has the future of his technology rather secured as well.

The option is best for the licensee. It is as mentioned a way for him to buy time. Even if the results from the trials that the licensor shall complete are positive, he does not have to exercise the option. Prior to the moment when he must decide whether to exercise the option or not the strategies of the company can have changed as well as the order of priority of projects or the licensee may have found more interesting projects to license in. But since he pays a fee for having the option, it is likely that the licensee will exercise the option if the result of the licensee's development is found positive.

As mentioned earlier, two of the license agreements we have studied are nonexclusive. In these the licensor is a university or a not-for-profit corporation, in both cases they are American entities. In both agreements the licensees are companies, but of what size is not possible to determine. One can only speculate why the licenses in these agreements are nonexclusive and not sole or exclusive. It is though interesting to note that the licensees are entities that are not profit driven. In the preamble in one of the agreements it says:

> "Licensor desires to have the Invention(s) perfected and marketed at the earliest possible time in order that products resulting therefrom may be available for public use and benefit."

Perhaps these academic and research driven actors are more interested in spreading knowledge and making their technology marketed and accessible than to earn money on their knowledge. Bringing research and knowledge forward is perhaps more important to them than to maximise their own economic benefit. The quotation above indicates that this could be the case, though nothing of course can be said for certain.

The licensee is in all the ten agreements that contain an exclusive license a company. In five cases the licensee is a large pharmaceutical company and the licensor is a smaller research or pharmaceutical company. We have earlier mentioned that larger firms often uses smaller ones as sources to get access to new knowledge. These agreements are examples of such knowledge transfer from smaller to larger firms. For the smaller firms the license is an advantageous means to get their technology into the complex commercialisation machinery, hopefully on its way to a global commercial sale. If the agreement is advantageous for the licensor does however not depend so much on whether the license is exclusive, sole or nonexclusive. It is often other regulations in the agreement that outlines the specifics of an agreement. It can for example be a matter of how big influence the licensor has of the development and commercialisation activities of the licensee or monetary regulations.

In another exclusive license agreement the character of the parties is the opposite, than in the five agreements mentioned above. Here it is the large pharmaceutical company that is the licensor and the licensee is also a pharmaceutical company but of a smaller size and more

specialised. In this case the licensor uses a smaller more specialised company to develop a certain innovation that it believes the licensee has a greater potential to do something of. Perhaps it is not economically advantageous for the licensor to continue the development of the innovation internally. The licensor also has an option for one of the formulations of the innovation. Through this regulation the licensor can see how the development turns out for the licensee and then decide whether he has a further interest in the innovation or not.

In two other exclusive license agreements the licensor is a group inventors[101] and the licensee is a company. These companies acting as licensees in these cases do not seem as big as the licensees seem to be in the earlier mentioned five agreement. These licensees can even be intermediary firms not interested in doing the commercialisation by their own. It can instead be their aim to sublicense the rights the a third party that then will handle the commercialisation. It would in that case confirm what we earlier have discussed under section 5.3.1, that single researchers seem to prefer to license their innovations to small companies instead of to the large multinational ones. This can though be a question of access as well. Perhaps it is not easy to get in touch with the large firms. Their size may also frighten the researcher, as well as their administrative machinery. Nothing in the two agreements indicates though that the licensees are intermediary firms. The contrary is neither indicated. In one agreement there is no right to sublicense. This would point towards that it is the licensee that will perform the whole commercialisation of the licensed rights.

In yet another agreement the parties are two pharmaceutical companies and they appear to be of similar size. They are though not competitors since they are active in different parts of the world. They will perform research together that will be based on an invention of the parties, but it is still the other party that is the strongest one in their relation. The agreement is clearly more advantageous for him. This party's knowledge seems to be very important for the collaboration and this is probably the reason why he is the most favoured party. It is otherwise difficult to understand this inequality.

In the two remaining exclusive license agreements both the licensor and the licensee are companies. In one of them the parties have earlier performed research together and the license agreement concern the licensor's share of the joint development. In this agreement the licensor has some connection with a university. In the other agreement both parties are active in commercialising pharmaceuticals. They are though not competitors. As in the agreement mentioned in the paragraph above they are active in different parts of the world. In both these agreements the licensor is active as a commercialising actor in Asia. Besides what just have been mentioned, not much can be understood regarding the parties' characteristics from these three last discussed agreements.

5.8.2 Geographical field of use

In most of the licenses we have examined the geographical field of use of the license is worldwide. It is eight of the exclusive licenses that have this extensive field of use. Hence none of the nonexclusive licenses are expressly worldwide. One is though almost worldwide since the territory includes all countries where protection exists except in those countries expressly excluded by the licensee by written notice. In another one the geographical field of use of the license is neither certain, since nothing is explicitly stated. The licensor is though an American university, the licensee is an American company and the license concerns a US

[101] Which is not the same in the two agreements.

patent. This would probably mean that the license only is applicable in the US. But what will happen if the patented technology will be patented in another country? In this case the time for such an application in other countries seems to have expired and no protection in other countries are mentioned. This type of uncertainty is though very unfortunate and unnecessary. It could easily be supplied by a short sentence in the agreement.

In the agreements, which do not give the licensee a worldwide license, the granted territory is specifically defined, such as certain countries or areas. Only in two agreements with an exclusive license the territory is not worldwide. The specified territory contains however in both almost all countries. In both agreements, though they do not have any connection, the licensed territory includes all countries of the world except some specifically mentioned countries in Asia. In these agreements where the license is exclusive just in a specified area this is because the licensor himself is active in the market. Therefore an area is excluded from the licensee's exclusive territory. In this area where the licensee does not have the exclusivity the licensor maintains the right to use the licensed rights. In both the agreements the licensor is active as a commercialising actor in Asia.

In the agreement where the license is partly exclusive and semi-exclusive there are two areas defined – one exclusive and one semi-exclusive. The exclusive area is defined negatively as all countries of the world except the semi-exclusive territory. In this territory the licensee has the exclusive right to commercialise the object of the agreement. The semi-exclusive territory is defined as one specific country. This territory can though be expanded if the licensee does not fulfil certain of his obligations related to the agreement. That a country can become included in the semi-exclusive territory can therefore be seen as a means of exerting pressure on the licensee to duly perform the agreement. In the semi-exclusive territory both the licensor and the licensee may commercialise products emanating from their relationship. We do not know which country that is the specific country forming the semi-exclusive territory but it is probably an "important" country when it comes to commercialisation. The licensor is not a commercialisation actor; it is a research firm, only engaged in R&D. This firm will therefore probably not do any commercialisation by its own in this territory; it is most likely that the licensor will grant another company a license to perform this commercialisation.

The agreement just commented has as mentioned above a special license regarding the field of application outside the field specified in the agreement. The license in this part is defined exactly as the main license.

5.8.3 Medical field of application

The field of application of the license varies a lot in the examined agreements; this is of no surprise since the agreements probably concern totally different medical fields. Only in two agreements it is specified that the license apply to all indications, both these are exclusive license agreements. One agreement is silent on this point, which is an unnecessary lack in the agreement that absolutely should be avoided. All the other agreements have a specified field of application. This specified field seems to be quite large in most cases, such as "therapeutic and/or preventative use in mammals to treat diseases" or "the prevention, diagnosis, control or treatment of any human or animal disease or condition".

The extent of the field is though quite difficult to evaluate for a person not familiar with these kinds of biotechnological or other scientific terms. In a few agreements the field is delimited to apply to a certain disease or condition. In one agreement a possibility to expand the field of

use is declared. Two agreements also contain regulations regarding the field of application not relevant in the present agreements. Both these agreements also include development cooperation and this is why other field of applications must be regulated as well.

The kind of medical field of use the agreement concerns does not have anything to do with whether the license is exclusive, nonexclusive or sole. It only relates to the licensed knowledge, what field of application that is possible and interesting for the knowledge.

5.8.4 Activities included in the license

The scope of activities included in the license is in most agreements extensive. It is also pretty much the same activities that are mentioned. Only in one agreement nothing is mentioned on this point. The most frequently mentioned activities are to sell, to use and to develop. These activities are extensive ones. They allow the licensee to perform all the important activities that are connected with the development and commercialisation of a pharmaceutical. No differences between the different kinds of licenses could be found regarding what activities that the agreement enclosed.

What activities that are included are in the agreement is very important. It is these activities that decide what the licensee is allowed to do with the licensed object. These decide the practical scope of the license. The licensee is not allowed to perform any activities not mentioned in the agreement. Hence, even if an activity is not included in the agreement, the licensee could argue that the activity must be considered to be included since the license and the activities therein included otherwise would be practically impossible to use and perform. The extent of such an argument can though not be regarded as great and a court would probably be reluctant to accept it.

5.8.5 The right to sublicense

The license agreement may also include authorisation for the licensee to grant a sublicense. A sublicense is a license granted by the licensee of the main license to a third party. The sublicense is legally a separate license agreement but it is in fact depending on the main license agreement, since the sublicense cannot be more extensive than the main license agreement. Permission from the licensor is required to be able to grant a sublicense. A sublicense can, as the main license, be nonexclusive, sole or exclusive.[102]

If such an authorisation is not specifically declared in the agreement the licensee has no right to grant a license to others containing the granted license. He can though of course obtain the licensor's permission separately, later when and if he wishes to sublicense his rights. In only two of the agreements we have examined there are nothing stated about sublicenses. Both these are short and rather unclear agreements. In the others sublicensing is permitted, though prior approval from the licensor is required in one agreement. In another it is only permitted to sublicense subsidiaries and in three agreements sublicensing to affiliates are permitted, but sublicenses to others require approval.

This seems to show that the right to sublicense is common. The licensor wants however in most cases to have some sort of control over whom the sublicense is given to. Even if the licensor does not oblige that his approval is given first, he wants to have information of the

[102] Sandgren, 1974, p 65

sublicense in most cases. When the licensee has an unlimited right to grant sublicenses it does seem that the licensor looses a certain control over the granted rights. Even if it always is the licensee that is responsible for the fulfilment of the agreement in relation to the licensor even if he has sublicensed, it is a risk for the licensor that his intellectual property will be connected with the "wrong" actors. This can lead to badwill for the licensor. For this reason it appears to be better to tie a requirement of an approval to the right to sublicense, at least when sublicensing is not made to affiliates or subsidiaries of the licensee.

There does not seem to be any difference regarding the right to sublicense if the license is exclusive or nonexclusive. Neither seems it to be any difference depending on the characteristics of the parties. Probably the regulation of these matters depends to a certain extent on the awareness of the licensor of these problems. As mentioned the best solution should be to allow sublicensing to affiliates, after a written notice of the sublicense from the licensee, and to require an approval if sublicensing is being made to another third party.

5.9 Prosecution and maintenance of intellectual property

There must always be one of the parties that are responsible for the intellectual property. In this case intellectual property only means patents. Someone has to see to that patent applications are being filed and adequately prosecuted, that the patents are maintained and take care of the correspondence with the different patent offices.

It is also important that a patent do not lapse by mistake and that someone handles the application for patent term restoration. Most naturally seems to be that the licensor takes care of all these things since the patents or patent applications are originally his, but this is not always the case. How these questions are regulated in the agreement mainly depends on how close the interaction between the parties is and how active the licensor will continue to be. It also depends on whether the parties do research or development together, since the liens between the parties in that case are tight.

When the license is nonexclusive it is the licensor that is responsible for the intellectual property. This is of course the most natural regulation since the licensor maintains the full right to his property. In one agreement granting a nonexclusive license it is also the licensor that pays the costs for the maintenance of this property and in the other the licensee shares the cost with other licensees, to the same property, until his sales in his territory reaches over a certain amount.

In the seven agreements where there is no joint development and the license is exclusive it is the licensee that is responsible for the patents in three cases. In these agreements it is also the licensee that stand the costs for these patents. The license is in all these three agreements worldwide. Since there are five exclusive worldwide license agreements, it is hence only in two of these the licensor has kept the responsibility of his patents. Why it most often seems to be the licensee that has the duty of managing the intellectual property may due to that it is the licensee that has taken over the development work for a specific compound or substance in a specific field. The licensor is consequently not so involved any more in how and where his intellectual property is protected. Even if it is the licensee that holds the responsibility of the licensor's patents he has to inform the licensor of all his actions taken regarding these. He often must take consideration to the licensor's opinion in these matters as well.

Which one of the parties that is responsible for the prosecution and maintenance when the

licenses are exclusive and worldwide, seem more or less to be a question of practical importance. It does not affect the use of the patent rights. Therefore it should be the actor, which has the best possibilities to handle the responsibility of the patents that should have this task. When the licensee is the responsible one this seems often to be the case when the licensor is a research institution or a group of scientists and is not profit-driven. These actors are probably more interested in research than in commercialisation, including handling with patents. It is however important that the party not having the responsibility have an opportunity to take over this duty if the other party fails in his obligations. Such an opportunity is, as we shall se further on, common.

It is in three agreements the licensor is responsible for the patents when the license is exclusive. Here the licensor bare the costs in two cases and in the other the costs are shared between the parties leaving the licensor with the largest part. In one of these three agreements the geographical field of use is not worldwide and in another one the field of application is limited to a certain disease. In these two cases it is natural that the licensor maintains the responsibility over his patents, since he can grant additional licenses to other parties. The license in the third agreement is both worldwide and encompasses all indications.

Another exclusive license agreement appears to state that the licensee is responsible for all *future* applications and patents. The exact wording is:

> "Licensee shall file, prosecute and maintain all future applications and patents covered by the Patent Rights."

The quotation seems to imply that the licensor remains responsible for the background rights consisting of licensed patents and applications. But this is not clearly stated anywhere in the agreement. How the licensee shall perform his patent obligations and that he shall bear the costs for the patents is though clearly stated. Whether this means that the licensee will be responsible for the patents the licensor has filed is uncertain. The licensor is a group of inventors, they seem to be independent researchers, and the license is worldwide. This point towards that it is the licensee who is responsible for the prosecution and maintenance of all granted patents.

To let the licensee be responsible for the maintenance of the patents does not have to imply that the licensor looses control. Often the licensor have set up time limits within which the licensee must act, for example to apply for patent in certain countries. The licensor can also specify the countries in which the licensee must apply for patent protection. In all cases the licensee is obliged to inform the licensor of all his activities relating to prosecution and maintenance of patents and this together with an opportunity for the licensor to take over patents if the licensee let them lapse gives the licensor a satisfying position.

In agreements that contain some sort of collaboration research the background and the foreground rights have to be distinguished. Background rights are intellectual property rights owned by each party at the start of the program and foreground rights are intellectual property rights generated out of the program. In the four agreements where we found a joint development program the licensor and the licensee are respectively responsible for their own prior applications and inventions, that is their background rights. When it comes to the joint inventions the licensee is responsible for these in one case and the licensor in two. In the forth agreement there is a joint development committee which decides in each case who to be responsible depending on whether the application is going to be made with respect to the licensee's or the licensor's intellectual property. This refers as stated only to the responsibility

of the intellectual property not the ownership of it. The ownership of knowledge developed within collaboration research has been discussed earlier under section 5.7.4.

As pointed out above it is important that the party not responsible for the prosecution and maintenance of the intellectual property have an opportunity to take over this duty if the other party fails in his obligations. Such an opportunity does not exist in the nonexclusive licenses. This is of course fully understandable, since the licensee in these agreements often is just one in a multitude of licensees with the same rights. In the other agreements we have studied such a possibility to take over the responsibility is however common.

In all the other agreements, except in one, the party not responsible for the maintenance of the intellectual property has a right to take over an application or a patent if the other party intends to let it lapse in one way or the other. Often there is an information duty for the responsible party stating a certain time limit within which he must inform the other party of his intention of letting a patent expire. How the responsible party should act when he plans to abandon or let a patent lapse is in most agreements very clearly stated in detail. The party has to inform the other 30,60 or 90 days prior to the deadline when the action in relation to, in most cases, a patent office must be taken. In four agreements no such specific time limit is declared, but the other party still has the possibility to take over the responsibility. One of the agreements states that the parties should discuss if, in this case, the licensee may take over the responsibility in each relevant case.

In two agreements when it is the licensee that is responsible and the licensor decides to take over, the license in respect of the specific patent becomes nonexclusive. In another agreement the license ceases. Such regulations are important to have. If the licensee is truly interested in the patents he would not in these cases abandon them or let them lapse. By making the license nonexclusive or let it cease in respect of the specific patent, the licensor can grant a license to a third party. Such a regulation should hence always be included in these cases, since it allows the licensor exert a certain pressure on the licensee and his performance.

An agreement in which it is the licensee that has the right to take over the responsibility from the licensor, the licensee has the right to deduct any cost he will have in connection with the patents from the royalty payment. Some agreements are though silent on the point what happens to the former responsible party's rights in the patents when the other party takes over the responsibility. This is of course unfortunate and should be avoided.

Only one agreement seems not to include, as mentioned earlier, an opportunity for the other party to take over the responsibility of patents. This agreement contains a joint development. The wording is though very brief and not very understandable. It is stated that the licensee has a right to terminate all of its obligations regarding the patents and that he must inform the licensor

> "60 days prior to a deadline for taking any action that must be taken in order to preserve the owner's rights in such Patent".

Upon such notice the licensee's rights, licenses and obligations under the agreements in respect to such a patent shall terminate. The regulation also concerns the joint patents. Probably it is indicated that the licensor takes over the responsibility of the affected patent, though not clearly expressed.

As a summery it can be said that if the licensor has totally granted his rights to the licensed

patents and applications to the exercise of the licensee, meaning that the license is exclusive, worldwide and concerns all relevant medical fields of application, it is not so important which of the parties that is responsible for the maintenance of patents. It should be the party possessing the best possibilities to handle this task that is responsible. If the license is restricted in some way, either to what concern territory, medical field of use or the type of the license, it is most natural that the responsible party is the licensor. The most important is however that the party not responsible has an opportunity to take over patents if the license is exclusive and if the other party intends to let them lapse of will abandon them.

If it is the licensor that takes over the responsibility from the licensee regarding one or several patents this should also be connected with some sort of consequence for the licensee. Whether the license in respect of the relevant patent(s) shall become sole or nonexclusive or terminates depends on how serious the licensor consider it to be that the licensee let the patent(s) lapse. It is important that these questions are regulated in the agreement in order to avoid disagreement when the parties are in the actual situation.

5.10 The regulation of improvements developed by either party during the term of the agreement

When a license agreement is being established between the parties it is the rights existing at that moment and defined in the agreement that become the object of the license. Both the licensor and the licensee can though develop improvements of these rights during the term of the agreement that may be of interest to the other party. Having access to the improvements that the licensor may develop can of course be of a great importance of the licensee and it strengthens the position of the licensee. It is better for the licensee if this already is regulated in the original license agreement instead of having to negotiate for a new license if the licensor has further developed his technology. It can also be of interest of the licensor to get access to the improvements the licensee may develop.

When the parties have a joint development the improvements and inventions made within the development program are already regulated in the license. It also seems to be common that improvements made by the licensor during the term of the agreement are automatically included in the granted license. This is at least the case in three of the four agreements that we have examined.

In one agreement improvements owned by the licensor are automatically within the license, since inventions and information

> "now and hereafter owned by Licensor or under which Licensor has, or may in the future have, the right to grant licensed to Licensee that are used or useful in the use, manufacture or sale of Licensed Products"

is included in the definition of the object of the license. This is an easy way to include all improvements in the license. In this agreement the licensor also has access to improvements developed by the licensee. He obtains a sole, worldwide license to the licensee's improvements to manufacture products and a nonexclusive, worldwide license to sell product within the medical field of use of the license. The licensor then also is granted an exclusive, worldwide license to these improvements to manufacture and sell products in other medical field than that specified in the agreement. In this agreement both parties will hence have good access to the other parties improvements. It is also an agreement in which both parties are active in a continuant development of pharmaceuticals.

Also in another of the development agreements everything developed by the licensor during the term of the agreement relating to the compounds or products that is the object of the agreement will automatically be within the license. The licensor has a right during the term of the agreement to use all information developed by the licensee that is related to the relevant compounds or products. In the third agreement the license includes all know-how and inventions owned or controlled by the licensor during the term of the agreement, which are found necessary for or useful in the development or the sale of the licensed products. The licensor will have a limited access to development made by the licensee, since he is granted a nonexclusive, worldwide license for use outside the medical field of the agreement. In this license joint developments as well as inventions and know-how developed by the licensee in connection with the performance of the research program is included.

The fourth agreement seems only to include improvements made jointly by the parties and not improvements made solely by either party during the term of the agreement. But the definition of the object of the license relates to some extent to another license agreement established between the parties prior to the agreement we have examined. Unfortunately we have not had access to this previous agreement. The difference between this last mentioned agreement and the other three is that it is exclusively, or at least mainly, the licensee that will commercialise the products emanating from the collaboration in the first three, but in the fourth the parties have divided the commercialisation in the world between them.

In nonexclusive license agreements it is probably more interesting for a licensor to obtain access and rights to improvements that the licensee may develop than if it concerns exclusive licenses. Such an access is often regulated through a “grant back” clause, which gives the licensor a license to an improvement the licensee develops. This granted license might include the right to grant sublicenses, which then makes it possible for the licensor to sublicense the improvement to other licensees.

Both nonexclusive license agreements have some sort of regulation regarding improvements. However none of them include a grant back clause. In fact improvements made by the licensee are not mentioned at all in these two agreements. It is though not possible to state that this should imply that grant back clauses are uncommon in nonexclusive license agreements. Our basis is far too limited to be able to make such a conclusion. Perhaps it depends on that the licensors in both these agreements are actors connected with the academia, which do not to the same extent as profit-driven actors involve themselves in their licensees’ commercialisation activities.

Improvements developed by the licensor are however mentioned in both the nonexclusive license agreements. In one they are included in the granted license, since patents now or hereafter owned or controlled by the licensor being related to the invention of the agreement are included in the license. In the other agreement the licensor shall bring any new invention related to the licensed technology to the licensee’s attention. The licensee will then have an opportunity to negotiate for a license. The licensor is in this case a university and it is stated in the agreement that this commitment to inform the licensee of any new inventions is subject to the licensor’s obligations to sponsored research. The regulations of eventual sponsored research may hence restrict this commitment and it is not possible in advance to estimate the importance of the licensor’s commitment.

In the agreement proposal of a nonexclusive license agreement that we have had access to, it

is interesting to notice that improvements are quite differently regulated compared with the other agreements, both nonexclusive and others. Improvements are very well regulated in this agreement proposal. According to the text, the licensee will have access to all improvements, without an increase in the royalty obligation, made by the licensor during the term of the agreement. The licensor is entitled to obligate the licensee to make use of such improvements. The licensee may however not undertake any improvement related to the licensed object if not a prior approval from the licensor is obtained. If the licensee is allowed to make improvements, these may be freely used by the licensor. The licensor is also entitled to patent such improvements without being required to make any payment to the licensee. This last regulation appears very advantageous for the licensor. But then we must bear in mind that this is how the licensor wants the agreement to be. Whether he will succeed in having this proposal of regulations in a final draft depends on the value and potential of the licensed object and probably also of the characteristics of the licensee. We have though not found any agreement with such a strong position for the licensor regarding improvements made by the licensee in any other of the studied agreements.

The exclusive license agreements show a rather divergent picture of the regulation of improvements. But it is only in one nothing is mentioned regarding improvements. In one agreement both parties obtain rights in the other party's improvements during the term of the agreement, since a mutual nonexclusive license is granted for developments during the contract. This license is hence a sort of grant back clause. This nonexclusive license is though quite complex and we will not go further into it. Improvements made by the licensor are mentioned in two other agreements. The licensor's improvements are automatically licensed to the licensee in one and in another the licensee has a right of first refusal to negotiate for any invention the licensor develops that relates to the licensed rights.

Improvements made by the licensee are only explicitly mentioned in one agreement. These are regulated in a grant back clause. The licensor is granted a nonexclusive license to the improvements of the licensee for internal research use only. And in another it is explicitly stated that the licensor may not perform any research that is related to the licensed product or compound during the term of the agreement.

We find it appropriate to let improvements be included in the definition of the licensed object, if improvements made by the licensor are to be included in the license. They will then be automatically included in the license. It also seems quite common to regulate improvements in this way. This is done in six of the studied agreements, which all are exclusive with and without joint development. In all these agreements the licensee is a pharmaceutical company and in four of these six the licensee is a large multinational company. Since improvements may be of large significance for the licensee, he should, during the negotiating of the agreement, bring up to discussion the right to get access to improvements done by the licensor. An absence of such a right to improvements can result in that the licensee cannot develop and commercialise the licensed object optimally. Obviously the companies in the pharmaceutical industry, at least the multinational ones, are well aware of the importance to have license rights to improvements and have seen to that these are included in the object.

Grant back clauses giving the licensor access to the licensee's improvements are particularly interesting if the license is sole or nonexclusive or not worldwide. From the licensor's point of view it should always be of great interest to have access to improvements done by the licensee if the licensor performs activities related to the licensed object. Regulations regarding

improvements made by the licensee are, as we have seen, not very frequent in the agreements we have examined.

A good solution if the parties do not want to regulate improvements in the agreement, but they still do not want to leave it totally unregulated, could be to insert a regulation in the agreement stating an obligation for the inventing party of giving the other party notice of the improvement and an opportunity to negotiate for a license. It does though not have to be an obligation for the inventing party to notify the other one. Instead this notification can be regulated more or less as an option. For the other party this possibility to get access to new knowledge could either just consist of a right to negotiate for a license or he could have a right of first refusal regarding the relevant the improvement. It is for this notified party better if he does not have to negotiate before he gets access to improvements. The optimal situation is of course if he is free to choose whether he is interested in the relevant improvement or not.

5.11 Regulations controlling the performance of the other party

5.11.1 The object and characteristics of performance obligations

Under this section we treat performance clauses, but what we here call performance clauses is no homogenous type of clauses. There is even not any clause in the agreements, which has "performance" as its heading. What we classify as performance clauses is rather a certain type of regulation. It is the type of regulation in which the licensee, or more rarely the licensor, undertakes to perform some kind of activity in a certain way or use a certain quantity of effort in the usage of the license. Such regulations are used by the licensor to control the activities of the licensee, so that the licensee will fulfil what the parties agreed upon when they entered into the agreement. These activities relate to the development or the commercialisation. As mentioned a performance obligation can relate to the licensor's activities as well. This is though not very common, since it is not in all license relations the licensor is supposed to perform any activities. It is hence above all in agreements with R&D collaboration we find these types of regulations.

The performance obligations can be of very different kinds. Sometimes they are found in a specific clause; this is then often named "due diligence" or "best reasonable efforts". But more often they are found in the clause regulating the matter they relate to, such as "research", "commercialisation" or "regulatory filings". Some of them are very vague in their definition of the efforts the licensee shall undertake, while others have detailed regulation of what the licensee shall and must do.

It is in the licensor's interest that the rights he licenses to another are used in the best possible way. He wants to be sure that the licensed rights will go through the development and commercialisation that the parties have agreed upon. It is here the performance clauses play a central role. The performance clause is a very important instrument for the licensor when he supervises the activities of the licensee. It is probably the best and most important legal instrument when the licensor evaluates if the licensee has made an adequate performance. The performance clauses are especially important if the license is exclusive, since the licensor then is more dependent on the licensee than he otherwise would be.

In the licensor's point of view it is best if a performance clause is concrete. If it puts up concrete measurable goals, the licensor will have a greater possibility to put pressure on the licensee. If the said performance is not fulfilled by the licensee this may constitute a breach of

the agreement. The licensor can then be entitled to terminate the agreement. Another type of sanction that may be relevant if the licensee does not fulfil the requirements in a performance clause is the transformation of the license from exclusive to nonexclusive. The performance clause can therefore be a guarantee for the licensor not to get caught in a licensing relation that is not profitable for him or the licensed rights.

A negative aspect of a more detailed performance clause may be that it always is difficult to in advance put up precise time limits for activities during the development phase. If a project demands extra studies, trials or alike, which were not anticipated when the license was negotiated, the performance clause must be renegotiated in order to fulfil the licensor's requirement. This can be time demanding and difficult.

Licensees are often not very fond of detailed performance clauses. They normally prefer more flexible obligations. A wording like "best reasonable efforts" can then be more suitable. Such a vague performance duty may for example say that the licensee shall allocate adequate resources to perform research and development work as is reasonable for development of pharmaceutical products in a similar stage and with similar potential. A flexible performance obligation allows the licensee to maintain his strategic freedom to a larger extent than otherwise. Here follows an example of a performance agreement, which is not detailed:

> "The Licensee represents and warrants, … , that it will devote such efforts and resources to develop, introduce to the market and commercialize the Licensed Products as it normally devotes to the development, introduction and commercialization of its own products having a similar potential of the Licensed Products."

A difficulty with the more vague performance clauses is that they always have to be interpreted and evaluated. If the licensor judges that the licensee has not fulfilled the obligations established in the contract it is not likely that the licensee is of the same opinion. The clause has to be interpreted in the concrete situation and this makes it a rather uncertain security for the licensor. The flexible performance obligation gives hence the licensee a larger scope of freedom of action, but it also tends to put the licensor in a more uncertain situation. Since the licensee always may change the order of priority of its project or his overall business strategy, the detailed performance clause is often preferable for the licensor.

How one party controls the activities of the other party through performance clauses is regulated in many different ways in the agreements we have studied. Many similarities can though be found. It is only in two of the agreements studied where no performance obligation was found. One is an exclusive license agreement and the other is nonexclusive. It is however interesting to notice that the licensor is a group of inventors in the first case and a university in the other. This may indicate that these types of actors are not yet very good at writing agreement and see to that their interests are protected in the best possible way.

5.11.2 Performance clauses relating to research collaboration

In the four agreements, which include joint development, there are performance obligations for both the licensee and the licensor. In one agreement both parties have exactly the same obligations, both regarding research and commercialisation. This is in the agreement that is a cross-license in which both parties more or less can be seen as licensee and licensor. The obligations relates to both research and commercialisations and read as follows:

> "Each party shall use Reasonable Efforts to conduct and complete such tasks and obligations and otherwise to achieve the goals of the Research Program."
> "Licensor/Licensee agrees to use Reasonable Efforts to develop such Collaboration Products and to market and sell in the Licensor's/Licensee's Territory such Collaborations Products develop by Licensee/Licensor."

In this case "reasonable efforts" is defined elsewhere in the agreement, together with other definitions. In this agreement, as in many others, reasonable efforts means efforts and resources commonly used for research, development and commercialisation of products of a similar stage in its life cycle, having similar potential. This clause is quite vague since no time limits are defined, nor any sanctions if a party would not fulfil its obligations.

The obligations of both parties are more detailed in the other joint development agreements. In these the obligations regarding research and commercialisation are divided. Therefore the parts that concern commercialisation will be commented later on, under section 5.11.4, together with the other license agreements.

In two agreements it is stated that both parties shall use best reasonable efforts to carry out the activities under the development program. If these requirements are not met the collaboration program may be terminated. In one agreement the commercialisation license will though not be affected by this termination while the licensed rights regarding the particular compound shall revert to the licensor in the other agreement. In the fourth joint development agreement the licensor has an obligation to provide the licensee with information regarding manufacture and quality control. No obligations regarding either party relating to the research program is mentioned, which may seem peculiar. This agreement is a bit different compared with the others. The research is not made in collaboration to the same extent as in the others and it is the licensee that plays the main role. It is though stated that if the licensee does not start to conduct a clinical trials within the time frame set out in the research program, the licensor may conduct the trial at the expense of the licensee. This seems to be an adequate and very effective type of sanction in the case of the licensee's failure.

A regulation stating that both parties shall use best reasonable efforts to perform the activities under the joint development program, as found in the two of the agreements, is convenient to insert when the parties perform research together. The regulation may seem vague since it refers to "best reasonable efforts", but in these cases the program will define what each party shall perform and this will form the base of the meaning of "best reasonable efforts" in the particular case. Even if a party as a rule can terminate the agreement if the other does not fulfil his part of the agreement it is, for clarity's sake, better if the rights of a party in case of the other's non-compliance is defined in connection with the regulation concerning the obligations. Whether the party shall have the right to terminate the whole agreement, just the joint research or have other rights depends on how important part of the agreement the joint research is. The parties should however have such questions solved before they begin to perform research together.

5.11.3 Performance clauses relating to R&D performed by the licensee

Five of the six exclusive license agreements that do contain performance obligations for the licensee include obligations regarding R&D. Four of these five have rather vague statements, saying that the licensee shall use best respective commercially reasonable efforts to develop a product. Though this formulation may seem vague it is stated in two of the agreements that the whole agreement shall terminate if the licensee does not fulfil these requirements. In the

other two agreements the licensor has to rely on the normal termination causes, in this case material breach, in order to have the agreement terminated if the licensee does not fulfil the requirements.

In one of the agreements above mentioned, that does state that the agreement shall terminate if the licensee fails in his obligations, the vague formulation regarding best reasonable efforts is combined with a time limit when the licensee must commence clinical trials phase three. This regulation only relates some specifically mentioned compounds. If the licensee fails to begin the trials at the time mentioned the agreement shall terminate. The regulation helps to clarify the obligations of the licensee. The compounds that are part of this last regulation are also probably these that the licensor considers being the most important.

Though nothing specific is mentioned regarding if the licensee fails to comply with his obligations, one agreement contains an explanation of when the efforts of the licensee are fulfilled regarding one of the two formulations of the licensed product the licensee shall develop. This specifically mentioned formulation is the formulation that the licensor has an option to take over after the licensee has completed clinical trials phase two. The efforts of the licensee are evaluated at a certain date, at which the licensee must have started trials on humans or laid down a certain amount in the development of the formulation.

One of the five agreements has a detailed regulation regarding the efforts of the licensee related to R&D. In this agreement there are different fixed time limits at which the licensee must have identified a product, entered into human studies or filed an IND[103] and entered clinical trials phase three in a specific country. The licensor has the right to terminate the agreement in all cases if the licensee has not complied with the required efforts within the specified time and has not cured the deficiency after notice from the licensor. The time limits seem to be extensive. It is for example a date twelve years ahead regarding entering clinical trials phase three. The time limits can though not be extended. The parties to this agreement own the licensed patents together since they previously have performed research together. If this would make the licensee more willing to assume performance obligations seems though doubtful. Since the time limits seem generous the obligations on the licensee are probably not very demanding.

The performance clause found in the nonexclusive agreement only relates to R&D. The licensee must use best efforts to perform research and clinical testing. When the licensee shall be deemed not to have used such efforts is also described. It is the only agreement that uses expenditure amounts instead of defined activities combined with time limits in order to define the efforts required of the licensee. In this agreement it is hence not certain activities the licensee must undertake, it is certain expenditures. These “efforts” of the licensee are only evaluated the first two years of the agreement and if the licensee fails the licensor has the right to terminate the agreement.

To relate the efforts of the licensee with the expenditures he makes instead of the activities he performs seems strange and rather ineffective. How much a licensee pays for the development of a certain product does of course say something about how much activity he lays down in a project, but the expenditures probably vary a lot depending on the performer. If one could find certain natural activities or stages in the development of a pharmaceutical and instead relate these to certain dates or time limits, such efforts are more effective and more easily

[103] This shortening is explained at p 16.

evaluated. Such natural activities or stages could be the commencement of certain trials or the filing of IND applications in certain countries.

5.11.4 Performance clauses relating to commercialisation efforts by the licensee

Nine of the ten exclusive license agreements and the agreement with a partly exclusive and sole license have regulations relating to the efforts the licensee must undertake regarding commercialisation. Most of them are rather detailed regarding what activities the licensee must perform and at which time limits. However three of these ten agreements just refer to "commercialisation". The licensees in these agreements must use best reasonable efforts to commercialise a product. In two of these agreements no time limits are defined and nothing is either mentioned regarding what will happen if the licensee fails to undertake the efforts. In one it is even stated:

> "The decision to launch or continue to market a Licensed Product in a particular country in the Territory, shall be within the sole discretion of Licensee."

The licensee has hence a big scope of freedom and the performance clause should be regarded as very narrow. The licensor's control over the licensee's performance is limited. The licensor is a small intermediary firm and the licensor is a large pharmaceutical company. It seems that the inequality between these two parties stand out in this performance clause. The influence of the licensor must be regarded as too limited. It is better for the licensor if he has more control over the licensed knowledge after the agreement is signed.

In one of the three agreements that only refer to commercialisation efforts the licensee must be able to prove that he has or is attempting to commercialise a licensed product after both three and six years from the date the agreement is entered into. What such proofs can be are not explained and what it is the licensee shall do to fulfil these efforts is neither explained. If the licensee has obtained regulatory approval for market introduction in certain specified countries the licensor may though not say that the licensee has not fulfilled the requirements. If the licensee cannot show any proofs of commercialisation efforts after three years the licensor may terminate the exclusivity of the license and if the licensee cannot show any such proofs after six years the licensor may terminate the agreement completely.

The other agreements regulate, as mentioned above, the commercialisation efforts of the licensee more detailed. These efforts relate to the filing or the obtaining of applications for marketing approval, the launching of products and the selling and marketing of products. There are time limits connected with the obligation to file applications for marketing approvals in two agreements. In one of these the licensee must have filed an application in two countries within 15 years from the date the agreement is entered into. This requirement does hence not seem burdensome for the licensee, but if he fails the licensor has the right to terminate the agreement. The other agreement relates the time within which the licensee must file the application to the ending of clinical trials. In some countries the application must be filed within one year and in others within two years. If the licensee fails to file the application in a specific country and does not remedy his failure within a certain time the licensor has the right to co-market the product the application relates to in that specific country.

To relate the time limit to a specific event in the development of a product as is made in this last commented agreement seems more adequate than to decide in advance how many years the licensee may spend on development before a product must be ready for a marketing approval application. It must be very difficult in an early stage of a compound's development

to assume such a time limit. The latest commented agreement gives the licensee a greater scope of freedom regarding the time he spends on development work. The time limits could in this case also be extended if the licensee encounters delays that are beyond his control. The remedy of the licensor in case of the licensee's failure does not seem exaggerated.

Even if no time limits are defined within which the licensee must file an application of marketing approval, a failure to make such a filing can be combined with some kind of sanction. All the four agreements that contain a specific obligation to file such an application, but within no specific time limit, all combine this obligation with a certain right for the licensor if the licensee would fail. It must though be more difficult to evaluate if the licensee has satisfied the obligations. Or it is rather the time at which the licensee should have filed the application that may be difficult to decide adequately. There is a considerable risk that the parties will not be agreed on at what time the performance obligation shall be evaluated. If this is the case is seems that the performance clause to a certain extent has lost its object. If the parties most likely will disagree regarding the use and definition of the performance obligation, the situation is not very different compared with how it would be if no or a vague performance obligation existed. The parties will in both cases have a dispute regarding the performance of the licensee. Disputes are of no good and a well-considered and defined performance clause could prevent unnecessary disputes.

In five agreements there are time limits connected with the obligation to launch and make the first commercial sale of a product. This time limit is in all cases related to the time when marketing approval has been received. The period within which the licensee must launch the product is in the agreements six or twelve months from receiving the marketing approval. In some agreement this obligation to start selling the product only refers to specific countries while it in others concerns all countries where an approval has been obtained.

All the five agreements also have regulations concerning the event if the licensee fails to launch the product. In one the licensor may terminate the agreement. In two the licensed rights regarding the product shall revert to the licensor, in one the license regarding the product becomes sole and in yet another the licensor may co-market the product. The remedies in these four last mentioned agreement only relates to the country in which the licensee has failed to comply with his obligation to launch the product. An important remark must though be done regarding two agreements in relation to these rights of the licensor if the licensee fails. The licensor may not use his stated rights if the licensee can show that his decision not to launch the product depend on certain specified reasons. Such reasons are claims of adverse event, lack of patent protection and a not commercially acceptable price structure in the country concerned.

Inserting such reasons when the right of the licensor may be waived has of course a clarifying function. Regarding the first two mentioned reasons such a waiver could probably be obtained in the other agreements as well, if there was such a reason and the parties could negotiate about it. The last reason though is more delicate. It is not at all certain that the parties would have the same opinion regarding what a commercially unacceptable price structure is. But even when the possibility to refer to a not commercially viable price is stated in the agreement, the parties must agree upon if the specific price can be regarded as not viable. It is though much easier for the licensee to refer to such an event if it is stated in the agreement.

The rights of the licensor in case of the licensee's failure to make the first commercial sale vary, as has been shown, in the five agreements. That the whole agreement can be terminated

does seem to be unfair for the licensee. To the contrary, the sanction that the license shall terminate in respect of the product and country concerned seems totally adequate. With such a sanction if the licensee fails the licensor can exert a certain amount of pressure on the licensee and his performance.

Except obligations relating to marketing approval and the first commercial sale two agreements contain an obligation not to withdraw a product from the market once the licensee has made the first commercial sale. These are the same two agreements that include certain reasons that the licensee can refer to which deprive the licensor the rights he normally has when the licensee fails to fulfil his performance obligations. These two agreements also have same types of parties. The licensee is in both cases a large pharmaceutical company and the licensee is a research company.

At first sight it may seem strange that just two agreements contain obligations not to withdraw a product once it is launch in a certain country. Many other agreements do though have other more vaguely defined obligations for the licensee against which a withdrawal from a market probably would be considered as a breach. Such obligations are that the licensee shall “fill the market demand” or shall “develop each market to its full commercial potential”. The risk that a licensee would withdraw a product from a commercially viable market once he have obtained marketing approval and launched the product is probably neither considerable. Therefore seem the more vague obligations more adequate in this situation, than an obligation not to withdraw combined with exceptions as in the two earlier commented agreements.

Whether it is best to choose to insert in the agreement a very detailed performance clause with time limits or a more vague one is not easy to say. To include some sort of performance regulation, where the licensor has the possibility to express the expectations and demands he has on the licensee, is though to recommend. We believe that there should be a more vague performance obligation as a base and that this should be combined with more exact obligations regarding at least regulatory approvals and the launching of the product. The more detailed obligations should be combined with time limits. It is better if these are related to earlier events in the development process of the pharmaceutical, than to fix a date certain years ahead at the time of the establishment of the agreement. It is always difficult to decide such dates in advance when it comes to drug development and such dates also makes the obligation less flexible. If the licensor feels insecure whether the licensee will undertake such development activities as the licensor wishes he can always try to have both types of time limits included as alternatives. This way he can prevent that the licensee spends unnecessary time during the pre-clinical and clinical phases.

To have more defined obligations for activities in the pre-clinical or clinical phase is more difficult than it is for events that occur later on in the life cycle of a pharmaceutical. The time necessary for the development is always difficult to estimate in advance. If detailed obligations with time limits are to be inserted it is better if these are related to an earlier event in the development process, such as the completion of a certain trial.

We consider is advisable to have the rights of the licensor, if the licensee fails to comply with the stated performance obligations, clearly defined in the agreement. This makes the performance obligation stronger and it also has a clarifying purpose for both parties. What the rights of the licensor shall be relates of course to the obligation the licensee has failed to comply with. If it relates to an activity performed early during the term of the agreement, the right for the licensor to terminate the agreement does seem adequate. When it is a

commercialisation activity the licensee has failed to comply with, it appears to be more appropriate to relate the licensor's right to just the country concerned. Such as making the license sole, nonexclusive or terminate the license in respect of the country and product concerned.

5.11.5 Other regulations controlling due performance

Except in the four agreements with joint research, there is only one agreement, which does not contain any performance obligations for the licensor. This is in an exclusive license agreement between two pharmaceutical companies active in different parts of the world. The licensor has to use commercially reasonable efforts to maintain the trademark valid and effective and also to supply the licensee with the licensed compound, at least during the licensee's development process. These obligations of the licensor are quite clear. Nothing specific is mentioned regarding what shall happen if the licensor fails.

5.12 Responsibility and reporting of regulatory filings and approvals needed for development and commercialisation in license agreements

If the parties in a license agreement shall have any possibility to develop and commercialise the licensed knowledge and technology they have to obtain regulatory approvals. Filings for such approvals have to be done in each country where the parties want to do clinical trials or launch the end product. The approval needed for clinical trials is an IND and the corresponding approval for commercialisation in the market is an NDA[104]. Besides these two there are other governmental approvals that are relevant for the parties to obtain as well.

It is normally one of the parties that have the responsibility for regulatory filings and approvals. As a rule this party is the licensee. For the licensor in a license relation it should thus normally be of interest to be kept up to date regarding these approvals. But in a joint collaboration in R&D both should have the right to be informed since the committee usually coordinates these compulsory activities.

The regulatory filings and approvals are somehow regulated in nine of the studied agreements. Of these nine agreements one is partly sole and exclusive and the others are exclusive licenses. All the four agreements with joint development have clauses that are dealing with these filings and approvals. Irrespective of how the agreements are construed, either or both parties are as a rule responsible for the filings and they have to keep each other informed of such filings and approvals, including any communication with the regulatory authorities. The information duty regarding regulatory approvals can be found either separately or incorporated in other clauses, which normally handle clinical trials and/or commercialisation. As a rule it is the licensee that has the regulatory filing and approval responsibility, at least in the exclusive territory. These statements are based on the studied 13 agreements among which only four do not have any such information obligation. Two of these are nonexclusive licenses.

In the nine agreements, which have clauses of regulatory filings and approvals we found that the responsible party for such filings and approvals can be the licensee alone or the licensee and the licensor together. In two cases when both parties are responsible a development committee is involved as well. It seems to be a tendency that when the licensee has the

[104] This shortening is explained at p 19.

regulatory filing and application responsibility the licensee is a large multinational company. It is only in one agreement the licensee is a company of a smaller size in such a situation. However the responsibility of the licensee is not solely automatically linked with an exclusive license agreement with joint development, pure exclusive ones also give the licensee this responsibility. In addition it can be mentioned that when the licensee is the responsible party he is consequently also as a rule taking care of the trials and commercialisation activities for which the regulatory filings and approvals are required.

The responsibility of the licensee is to obtain regulatory filings and approvals that are important and needed for different trials and for commercialisation. There is also normally an obligation for the licensee to inform the licensor of any filings and approvals linked with the same responsibility. The requirement that lies on the licensor is to transfer important and necessary information relevant for regulatory filings and approvals to the licensee.

In two agreements in which the licensees are large pharmaceutical companies it is specifically expressed that the ownership of the regulatory filings and approvals shall belong to the licensee, even those that have to be transferred from the licensor. This does though not mean that the licensee not will become the owner of the filings and approvals of which he is responsible in the other agreements where such ownership is not specifically expressed. Since he has the responsibility he should also as a consequence receive the ownership of them, whether he is a large party or not. Regarding such filings and approvals that belonged to the licensor prior to the agreement and that shall be transferred to the licensee; the situation can however be different. The licensee then probably only becomes the owner if they are not seen as a part of the licensed object, meaning an asset of the licensor that the licensee through the license has a right to use.

One agreement where the licensee is responsible for the regulatory filings and approvals is a little different from the others regarding the information duty. Even if the licensee shall handle the IND filings and approvals there is no stated information duty for the licensee to the licensor of such activities. But to the contrary there is such a duty for the licensee concerning an NDA filing and approval. In all the other agreements the licensee has a reporting obligation to the licensor regarding all regulatory filings and approvals that are relevant for the specific agreement. This specific license agreement is optional, exclusive and worldwide and the licensee is a large multinational pharmaceutical company while the licensor is an intermediary firm. It is the licensee that shall perform most of the clinical trials and handle the whole commercialisation provided that he activates the option.

It seems like the licensor does not have an interest in the filings and applications of an IND, probably because they are not in this agreement related with any of his intellectual property. He has transferred this right to the licensee and let the licensee handle it independently. Regarding the licensor's interest in filings and applications for an NDA this interest is linked with the maintenance of his proprietary rights. The licensor has to file an application for patent extension to the FDA[105] in the US, 60 days after the NDA approval in the same country. A patent extension is often very vital for the holder of the patent, the licensor, since the effective time of the patent otherwise will be too short in comparison with the resource that have been input in the project to which the patent is relied. Obviously the market in the US for the licensed object is an important one for the commercialisation. These facts make thus the interest of the licensor to get informed of a NDA approval in the US comprehensible.

[105] This shortening is explained at p 19.

However the licensee should also have an interest in, almost the same as the licensor has, that a patent extension is being filed by the licensor since the license granted to the licensee is exclusive and worldwide. The licensee should thus report such NDA approvals to the licensor as much in his own interest as in the licensor's.

The four agreements in which the licensee and the licensor are responsible together for regulatory filings and approvals or in which they both have such responsibility, but for different filings and approvals, are two exclusive licenses with joint development and two exclusive ones without such collaboration. In two of these four agreements the development committee is involved regarding these regulatory filings and approvals. These agreements where both parties have the responsibility is construed quite different but the tendency is that the licensee and licensor shall both be responsible for and handle the regulatory filings and approvals that are required and inform the other of any such filings or approvals. This does not however mean that they do the filings together. They will of course take care of the filings and approvals that relate the most to their respective activity at the filing moment. Here is a quotation from an exclusive agreement where the licensee and the licensor have such responsibility together:

> "GOVERNMENTAL FILINGS. Licensor and Licensee each agree to prepare and file whatever filings, requests or applications are required to be filed with any governmental authority in connection with this Agreement and to cooperate limiting with one another as reasonably necessary to accomplish the foregoing."

As said above the licensee can be responsible for the obtaining of regulatory filings in one area and the licensor in another. This is the case in one exclusive license agreement with joint development. In this agreement the licensee, a large multinational company, has the major responsibility for the regulatory filings and approvals that are required for clinical trials and commercialisation. The licensee will take care of most of the R&D work and has an exclusive license regarding the commercialisation so this construction has to be seen the most appropriate. The licensor, a small research company, will on the other hand handle certain specified filings and approvals. The development committee is also involved and its mission is here to coordinate the parties to obtain the approvals needed for development and commercialisation and to take care of the exchange of information regarding the parties´ respective regulatory filings and approvals.

The duty to inform the other party has to be fulfilled not only after the filings have been done and the approvals have been received but even, if suitable, before any filings are sent or communicated with the relevant authorities. This obligation of prior notification is giving the parties a good opportunity to control each other's activities regarding development and commercialisation requirements. Maybe it should have positive effects if such a requirement were more frequently used in license agreements where either or both parties have to take care of and be responsible for certain regulatory filings and approvals. This could be a means to become more aware of each other's filing activities, which are very important for further development and/or commercialisation. An example how a clause may be written can be like this:

> "Cooperation and Sharing of Information. The research committee shall coordinate efforts to obtain both product approvals and manufacturing approvals and the parties shall provide reasonable assistance to the other in connection with obtaining such approvals. Each party shall provide copies or all filings with regulatory authorities to the other party, prior to filing if feasible. Each party shall keep the other apprised of the status of all planned clinical trials,

development strategies and approvals and each party shall have the right to attend meetings of the other party with regulatory officials."

Such a prior information duty of regulatory filings to the counterpart is also found in another similar license construction. This exclusive joint development agreement is special regarding the filing and obtaining of regulatory approvals because the licensee and the licensor has to give each other an approval before a filing can be sent to the relevant governmental authorities. We have not found a similar such specifically expressed required approval from the other party in any other agreement. The explanation can however be that the parties, both pharmaceutical companies active in different parts of the world, are both contributing with their respective knowledge and technology. Through the license agreement they are thus giving each other a right to use their respective knowledge and technology and they can actually be seen as licensee and licensor at the same time. By inserting such a prior approval obligation regarding regulatory filings and approvals they will have a large extent of control over each other's activities to file for and to obtain regulatory approvals, which are vital in order to perform development trials and lunching of the end product.

There is yet another agreement where the development committee is involved concerning the regulatory filing and approval activities. The license is exclusive without R&D collaboration, but the parties who are two pharmaceutical companies have established a development program and committee anyhow. It is the development committee that is responsible for the regulatory filings and approvals, which means that the parties are filing for and then obtaining such approvals together in the committee. The committee shall also have as a mission to be a forum for the exchange of information of the regulatory filings and approvals that have been done. A reason why the parties in this agreement have established a committee may be because the license is not worldwide and the licensor is active in development and commercialisation in the territory excluded from the licensee in the agreement. The licensor has therefore more interest in receiving information regarding the licensee's activities concerning filings and approvals than he otherwise would have.

To establish such a committee when the parties are responsible together for these activities required for development and commercialisation has to be seen as a good solution. Through the committee these required activities are handled and information of such activities received. The parties will be highly aware of the other party's actions and will consequently even have control over the other party. Maybe such a construction is something to consider for the actors, as we have found in our studied agreements only are pharmaceutical companies of shifting size, who in their agreements have an intention to regulate and to both take responsibility for regulatory filings and approvals.

The agreements, which have clauses of regulatory filings and approvals, are quite shifting in how detailed they are and what the parties are supposed to do. Apparently the licensor can better overview the licensee if the licensee has to report any filings and approvals relating to the licensed knowledge and technology. Also when the parties are responsible together for such regulatory filings and approvals the same interest in receiving information of these activities exists. The licensee can thus also have such a need of awareness of these activities as the licensor when the licensor is responsible for certain regulatory filings and approvals.

To have the right to achieve information of the other party's activities regarding filing for and obtaining regulatory approvals is vital since the license agreements are entered into in order to further develop and/or commercialise the licensed object. It is understandable that the licensor, who has given another party a right to use and exploit his intellectual property and

other related knowledge, has a large interest in how the licensee is doing and how he performs the granted rights under the license. In an agreement where the licensee is not the only responsible party for the required regulatory filings and approvals, the licensee has an interest that the licensor actually does the filings and achieves the approvals that are needed for the development and commercialisation activities that the licensee is supposed to perform. If the licensee does not receive such needed approvals he cannot continue with his activities and it can result in a great loss of money and goodwill. Such a reporting obligation can thus be seen as a practical, good and useful tool for the party or the parties in order to have control over that any action by the other party will not cause any damage to the own business activities.

There are also a number of license agreements among the studied agreements that do not have clauses for regulatory filings and approvals. We found during our study that the nine agreements in which the parties have regulated how regulatory filings and approvals shall be handled all have as their parties pharmaceutical companies, either large multinational or of smaller size, intermediary firms or small research companies. None of the agreements in which one party is a university, group of inventors or a non-profitable-company have such clauses. This party, originating from the academia, is in all these agreements the licensor. In total it is four of the 13 studied license agreements that do not have such regulatory filings and approval regulations. The two exclusive licenses of these four exceptions have as their licensed object both patents and know-how and the licensor is in both agreements a group of inventors. The two nonexclusive ones only have patents as their object and the licensor is a non-profitable-corporation respectively a university. The licensee is in all cases a company, most probably of a smaller size.

Is this tendency pointing at that when the licensor is originating or linked with the academia, meaning not as profit driven as the pharmaceutical companies the parties do not regulate regulatory filings and approvals? In all cases the licensee, the company, has taken over the further development and commercialisation of the licensor's knowledge and technology. The licensor's main goal is to spread the new knowledge so that as many as possible can make use of it. Their major interest is to receive a remuneration that will cover the discovery and early development expenses and of course even future R&D work.

To receive such remuneration the licensor needs to find a licensee willing to take over the commercialisation. The better reputation the licensor has as a researcher the easier he will find suitable partners. A researcher with a good reputation does not have to search for partners – these probably will contact him. When transferring the whole commercialisation on the licensee the licensor can spend all his time and focus completely on R&D work. This will of course favour his R&D work. However a researcher in the academia should perhaps try to attain more influence on the commercialisation of his licensed rights than he normally has today, even if it to some extent will decrease the resources and activities that can be put on the R&D work. When transferring everything to the licensee the researcher looses his control over how and if the licensed object will be commercialised. This can be a disadvantage since he then cannot affect or have any influence on the licensee's commercialisation strategies. It is however clear that a researcher within the academia does not normally strive for a huge income and for the creation of a successful business, as the companies do.

When the licensor is a university or alike he has thus obviously not an interest in any further control over the licensed invention. He is primarily a party that perform discovery, research and early R&D work. To receive information about regulatory filings and approvals is though not something that attracts him. This type of licensor has to find a company, with necessary

resources, that can take over and further develop and commercialise his invention, since the licensor is not able to do it himself. Then when such a party is found this party, the licensee, can independently perform such activities as the parties have agreed upon in the license agreement. The licensor is normally satisfied as well and can concentrate on discovering and developing new potential knowledge for future pharmaceutical products.

5.13 Regulating adverse events, which can cause a lot of damage and badwill to a party

> "Adverse Events shall mean any unintended and unfavourable sign, (e.g. an abnormal laboratory finding), symptom or disease temporarily associated with the use of a pharmaceutical product."

For a pharmaceutical company developing and commercialising a pharmaceutical it is very important to have up to date knowledge of how the actual product is conducting. Within the pharmaceutical industry it is not unusual that a product previously evaluated to have no risks at any time, during the development or commercialisation, can show signs of unwanted and dangerous adverse effects. As a rule it is the company from which the product originates that is the responsible party if anything goes wrong with the product.

If such adverse effects occur during the clinical trials, in the pre-marketing phase, it can be regarded less disadvantageous for the company than if they are discovered when the product is already launched in the market. During the clinical phase no consumers have got access to the product yet but in the other case the product is in circulation and the situation is then very serious. To avoid negative effects and badwill for the responsible company it is therefore important to report, control and stop a product consisting of a compound with adverse effects before it has been introduced in the market. A pharmaceutical containing dangerous substances can cause huge economical and geographical damages for the owner of the product. The owner should therefore be prepared if he finds himself in such a situation.

In general adverse events are only found in license and distribution agreements and not in pure R&D agreements. A clause treating adverse events is as a rule considered as a necessary element in a license agreement. Despite this fact many license agreements granted in an early development phase can show gaps in how such events shall be handled. Normally the parties then agree on how to report any adverse events in a separate contract signed later on.

A licensed product originates from the licensor and consequently he has the responsibility for it. As a rule it is thus the licensor that has the major interest to have control over any adverse effects regarding any of his licensed products. However it is the license construction that decides whether a reporting obligation is interesting for the licensor or not. If it is an exclusive worldwide license the licensor do not normally have an interest in any reporting from the licensee regarding any adverse events. This is because the licensor has then no product responsibility any more.

To the contrary the licensor do have an interest in adverse effect reporting when the license is territorially divided or nonexclusive. In this case it is very important that all the different licensees get information about any discovered and suspected adverse effects so that they can take necessary measures as quick as possible. One such measure is to report adverse events to the regulatory authority in each specific country where a licensee, developing or commercialising the actual product, is active. It is the party with the product responsibility that has such authority-reporting obligation. In a prolongation this lies on the licensor and

consequently it is he that must see to that every licensee gets information of any adverse effects in order to be able to meet up to the reporting obligation.

In two of the studied agreements a specific clause for adverse events is found. In one of these agreements the parties are cooperating in R&D through a collaboration license. In the other agreement the parties have a development program but there is no collaborating license despite all. What concerns the commercialisation the granted licenses are territorially sole and exclusive which means that the licensor has an interest in any eventual adverse events of the licensed knowledge, technique and the resultant product. The parties shall notify each other of any fatal and life threatening adverse events within a certain short period from becoming aware of such information. Other less serious adverse events and safety information relating to clinical trials or other activities during the pre- and post-marketing period shall first be reported by each party to the relevant and competent regulatory authorities and then submit a copy to the non-reporting party.

It can be said that the responsibility to take care of the registration of a product in a specific country often is linked with the obligation to report any adverse events to the authorities. Normally it is the licensee that handles the registration in his specific licensed territory and thus even the required reports. It is quite unusual that the licensor handles such responsibility obligations.

Even if the other studied license agreements do not contain any specific clause for adverse events or mention any such events, this does mean that the parties have ignored to consider and to regulate the question. As mentioned before adverse event issues are often treated in a separate agreement. Actually one of the studied agreements does have such an arrangement in which the parties shall agree on a plan how to handle adverse event reporting.

We have consistently through the answers to the questionnaire got the impression that it is very important to somehow regulate an obligation to report adverse events in a license relation. Therefore we do not consider the absent adverse events clauses as an evidence of that they have been ignored or forgotten. Obviously such issues are far too vital not to observe when transferring knowledge between the parties in the development and commercialisation of a new pharmaceutical. Most of the studied license agreements are in an early stage of the commercialisation process and this is probably one of the reasons why it is so few that have expressed clauses of adverse events. Moreover they are normally regarded more important in the marketing stage of a new pharmaceutical.

It is very advantageous for the parties of the license agreement to be the first to receive information of unexpected adverse events. By such an information duty between each other they will be the first to investigate such injurious information. If it turns out to be false information they will be prepared to defend themselves against accusers. In the opposite situation, when the information is correct, the parties will be able to act before anything happens or if it is already too late they have at least the opportunity to come out with the news themselves.

The licensor wishes that its licensed compound, technique, invention or patents would become a commercial competitive product without any unexpected adverse effects. Through the reporting obligation the licensor will receive information about adverse effects and has by this control over the licensed product. Especially when it comes to marketing of a pharmaceutical it is extremely important to have up to date knowledge of any suspected

information that can harm the reputation of the product and the company. Even the licensor wants to market a product without any adverse effects and the reporting obligation is also giving the licensee control over adverse events.

5.14 Early termination of a license agreement

5.14.1 Reasons that may give either or both parties a right to terminate the agreement before the term agreed upon has expired

The term of a license agreement can almost without exceptions be found in a special clause in the contract. If nothing goes wrong during the period upon which the parties have agreed to continue their arrangement, the agreement will expire on the termination date. But sometimes things do not proceed as the parties have intended. Then it is important for the parties to previously have regulated certain issues that either or both of them do not accept since this permits an earlier termination of the agreement.

In the 13 studied agreements we found two circumstances very frequently presented that are allowing either or both parties to terminate the agreement prior to the expiration date. It is not surprising that these two are material breach and insolvency or bankruptcy, since such circumstances are regarded serious in agreement relations. It is interesting to see which party that has the right to terminate the agreement when there is a material default or an insolvency or bankruptcy situation, because if one of the parties do not have such a right the position of that party is rather weak.

Material breach clauses were found in all the studied agreements. Both the licensee and the licensor have in general the right to terminate the agreement because of a material breach of the contract. In all the joint development agreements both parties have this possibility and all the exclusive licenses without joint development, except two, give the licensee and the licensor a right of early termination. In the two exemptions it is only the licensor that possesses the termination right for material breach. Regarding the nonexclusive licenses it is only in one, in which the licensor possesses the right, that both parties cannot terminate the agreement on account of any material default.

The agreements in which only the licensor has the termination right because of a material breach the licensors are inventors, a university and a company of undefined size, but probably small and research intensive. The licensees are in these agreements companies with an unknown size. Here a quotation from one of these agreements will be presented:

> "If Licensee fails to perform or observe any of the agreements, provisions, duties or obligations under the Agreement such as the timely reporting and payment of royalties, and does not remedy the failure within thirty (30) days after receipt of notice from Licensor, provided, however, that repeated failures by Licensee shall constitute an independent basis for the Licensor to terminate this Agreement."

It is interesting that the licensors, who is linked with the academia, in some agreements, have got such an advantageous right in comparison with the licensees, the companies. For licensors like this it should be a good idea to more actively set up similar requirements in their relations to the licensees. The academia is an important source of new knowledge and the actors within it or who are somehow linked with it should be more active to strengthen their position as a licensor. If the actors in the academia began to guard their interests more efficiently they

could probably relatively soon achieve a stronger negotiation position and have better possibilities to have influence on their own situation in the license agreement.

We found that if a multinational pharmaceutical company, an intermediary company or a company with certain significance is a licensee or a licensor; it has seen to that there is a possibility to terminate the agreement in occurrence of a material breach. Without such a right the party will not have a strong position in the agreement. It should be regarded as a huge disadvantageous not to have a termination right if the other party is materially breaching the license agreement. A requirement is also connected with this termination possibility. In all the examined agreements the defaulting party must been given prior written notice and has a right to cure the default within a certain period, which can alter in between 30 to 120 days depending on the agreement.

Clauses that treat insolvency and bankruptcy are not as frequent as those of material breach in the studied agreements. However it is normally both the licensee and the licensor that has the right to terminate on such reasons. In three of four joint development agreements the termination right belongs to both parties and in the fourth nothing is mentioned about insolvency or bankruptcy.

In the exclusive license agreements without joint collaboration in R&D three give the termination right to both parties, one only to the licensor, one terminates automatically if the licensee becomes bankrupt and in two there are finally no clause regarding termination upon insolvency or bankruptcy. The agreement, in which it is only the licensor that has the termination right, has, as its licensor a group of inventors and the licensee is a company with an unknown size. Here is a quotation from this agreement:

> "Licensor, at its discretion, may terminate the Agreement by giving notice to Licensee if there is a proceeding commenced against Licensee under any bankruptcy act under any present or future law for relief of debtors, or a receiver or trustee is appointed for Licensee or Licensee's assets, or an action or proceeding is commenced to dissolve Licensee, or Licensee makes an assignment for the benefit of creditors or ceases on business for any reason."

Regarding the nonexclusive licenses none of them have any such termination clauses. In such a license relation the licensor is normally not relying on only one licensee, the situation is therefore less sensitive since his knowledge and technology as a rule is commercialised by several licensees. However in the agreement proposal of a nonexclusive license that we have had access to, such termination rights are mentioned and both parties then have the termination possibility.

Whether the license is exclusive or nonexclusive the parties should regulate such issues if they want to prevent economical risks and eventual future disputes. Regardless what type of license it is, the party who wants to terminate the agreement because of insolvency or bankruptcy, that the other party is subjected to, usually has to give the counterpart a written notice in advance.

Another circumstance that we found relatively frequently in our agreements is termination without cause. In all the agreements with a clause like this it is the licensee that has the termination right. Such a right must be seen as an advantageous for the licensee but less so for the licensor. It is the licensee that has entered into the agreement and often takes high risks in order to further develop and/or commercialise certain knowledge and technology that belong to the licensor. If the licensee finds that he has no use of the licensed invention or cannot

commercialise it as expected he has thus a right to terminate the agreement even if the licensor has executed the agreement correctly.

Through such a termination right the licensee is not forced to continue an agreement that is not advantageous for him. Normally the licensor should though not have to worry if he knows that his licensed innovation is strong and have a good commercial potential that the licensee will not abandon. This can however be difficult to know if the invention is licensed in an early stage of the development process. A substance or product can furthermore suddenly show adverse effects or otherwise become not commercially viable or interested.

This right for the licensee to terminate the agreement without cause can be found in all the different types of licenses. It seems to be a tendency in the agreements, where such a termination right is established, that the licensee is a pharmaceutical company either large multinational or of a smaller size. The licensee is a large multinational company in one joint R&D license and in three exclusive agreements without joint development. The other agreements with a right to terminate it without cause have as their licensees also companies, but of which size was not possible to determinate. Three such agreements are exclusive without any R&D collaboration and two are nonexclusive. For the licensee there is usually an obligation to inform the other party in advance if there is a desire to terminate the agreement without cause.

The licensor in the agreements giving a termination right without cause for the licensee is as a rule more research-intensive actors such as smaller companies, a university or inventors. In one joint development license and three exclusive licenses, without such development collaboration, the licensor is a small research company. There are furthermore two agreements, one with R&D cooperation and one exclusive without, where the licensor is an intermediary firm. In two nonexclusive licenses and one exclusive the licensor is a university, inventors or a non-profitable-corporation. Finally there is also a large multinational company that is the licensor allowing the licensee to terminate the agreement without cause. An example of a clause is taken from the agreement with a group of inventors as the licensor:

> "Licensee may terminate the Agreement and the licenses granted under this Agreement by giving Licensor three (3) months prior written notice to Licensee."

When the licensee is a multinational company or a company of a larger size this party has seen to establish a strong position regarding termination without cause when it finds the contractual relation not further interesting or profitable. Obviously the larger party has a better position to negotiate such a right and the licensor never seems to have this termination ability. Probably this is due to that the licensor normally has the proprietary rights to the licensed knowledge and technology and it should be too risky for the licensee to invest in or otherwise involve himself in a new project if the licensor also had the termination right without cause.

There are of course other circumstances that can result in an early termination of the agreement provided that the parties have agreed upon such issues. It can be either or both parties that are granted such a right. For example the licensee has, in a nonexclusive license, a right to terminate the license if he after having scrutinised the list of other licensees and their activity areas, that the licensor has to supply the licensee with, finds the license unsatisfactory and non-profitable. Other reasons can be that the technology is not commercially viable, void patents, unrealised industrialisation or commercialisation and uncured breaches of certain warranties and efforts. Whether it is the licensor or the licensee that has the ability to terminate the agreement on such causes depends on the agreement.

In the agreements where the parties are performing joint R&D the research program has own regulations concerning early termination. Those termination grounding causes and which party that can terminate it is discussed earlier under section 5.7.5, that treats how the joint R&D activities are regulated and performed by the parties.

5.14.2 Effects of an early termination on a license agreement

5.14.2.1 Circumstances affecting the effects

From a commercialisation perspective, as this essay has as its main object, it is interesting to look at how the granted licenses and other rights will be affected by an early termination. If the license agreement is terminated by either party by any means the development and/or commercialisation activities cannot normally continue as previously. One party has terminated the agreement and has no intention or interest to uphold the contract intact. Therefore it should be of great interest for the parties to have discussed such termination issues during the negotiations of the agreement and have seen to have them regulated in the final draft. However it can be vital that some rights are maintained unchanged or otherwise with some restructures since there may have been a lot of development results and input of efforts and resources in the agreement which otherwise should be unused and not profited from to the largest extent possible.

In all the 13 agreements there is a clause, which deals with termination issues. The granted licenses and the other rights and obligations the parties have obtained through the agreement are of course the basis for how an early termination will turn out. In some agreements these clauses are very detailed and long while in others they can be short and sometimes almost empty. Regarding the agreements with joint R&D the consequences of termination are detailed and well considered. The nonexclusive ones are though in comparison relatively short. The reason for this divergence between these two types of licenses and why it is like this is that in a joint development license the parties are much more tied together when performing the development. Normally it is the licensor that has contributed with a lot of knowledge. Such collaboration will normally bring with it commercial results and it is of course interesting for the licensor and the licensee to know what will happen if the agreement is terminated in advance by either party. In a nonexclusive license the relation between the parties is not at all so tight and there are less, but not said less important, questions to discuss and to regulate.

As said before all the 13 licenses are different and have their specific object and the same is true regarding how a termination will turn out. Despite these differences there are though some grand similarities that can be distinguished. For example regardless of what reason that has caused the termination, regulations concerning development and commercialisation actions taken by either party in accordance with the agreement prior to the termination, meaning during the term of the agreement, will survive. Survive will also as a rule certain in advance specified clauses in the agreement, such as the obligation to pay royalties for sold quantities, confidential information, indemnification obligations, any right to use trademarks and names and usually also the ownership of the intellectual property. These mentioned features are important for the transfer of knowledge in order to commercialise an invention. If the parties have not in the agreement regulated which clauses that have to survive any termination it can be seen as a shortage in the agreement regardless the type of license.

Any termination because of a material breach, insolvency or bankruptcy, without cause or otherwise permitted in the agreement principally have different consequences in all the 13 agreements. Whether it is the licensee or the licensor who terminates the agreement by reason of any of those termination circumstances also affects the result of how the licenses and other rights shall be handled. It is common that two or sometimes even more conditions that give a termination right for either or both parties are put together and will thus have the same outcome. There is also a tendency that the result of any termination will differ depending on if the licensee or the licensor is the party who terminates the agreement, and consequently even whether the party with the termination right is a large multinational company, smaller pharmaceutical company, intermediary firm or with its origin in the academia.

It is thus the license construction of a license agreement that will decide and affect how the license(s) and the other to it related rights would be handled in case of an early termination. It seems that the parties as a rule have more or less discussed and in the agreement regulated these questions. Among the studied agreements there is only three agreements in which we did not find any clause regarding how the licenses and other rights should be dealt with in occurrence of an early termination. Of these three agreements, two are exclusive having as their licensor a company and a group of inventors. The third is a nonexclusive license with a US university as its licensor. Regarding the two licenses that are linked to the academia the reason for the absence of such an early termination clause for the licenses might be that the interest of the licensor is more to contribute to spread and make available new useful knowledge than to earn a lot of money on it.

5.14.2.2 Consequences of termination without cause by the licensee

Concerning the right for the licensee to terminate a license without cause such a right can be found in all types of the studied agreements. In two of the license agreements where the parties are performing joint development the licensee has an obligation to grant the licensor a certain license if he terminates the agreement. One of theses agreements is partly sole and exclusive and the other is exclusive. The licensee has to grant the licensor a nonexclusive worldwide license under his, during the agreement, developed technology to commercialise the compound or product, which was the object of the terminated agreement. Since the licensee was granted a worldwide, respective almost worldwide in the main agreement it is natural that these termination grounded licenses are worldwide too. The licensee also has an obligation to transfer important documentations and information as well as the rights that relates to the regulatory filings and approvals and to the licensed object to the licensor. Such a clause can read as follows:

> "Termination by Licensee … Licensee shall have the right to terminate this Agreement at any time upon six month's notice to the Licensor. … Licensee shall transfer and assign to Licensor all of Licensee's right, title and interest in and to any Licensee's Collaboration Technology and all data, reports, records, materials and other intellectual property owned or controlled by Licensee that relates exclusively to the Collaboration Compound and/or Covered Products; -- grant Licensor a non-exclusive license, solely for the purpose of Licensor's developing, making, having made, using, marketing and selling Collaboration Compounds and/or the Covered Products …."

In both these agreements the licensee is a large multinational company and the licensor a small research firm respective an intermediary firm. Since the licensee has the right to terminate without cause the licensor has to be granted something in return. As we have discussed before the size of a party does not mean that its negotiation position is weak. The large multinational pharmaceutical company do not license in if there is no need of such

action. In fact it is all the time searching for new knowledge with a commercial potential. The research company and intermediary firm are normally well aware of their importance and therefore they can as in these two licenses have negotiated such a nonexclusive license, which allows them to benefit from the joint development and to be active in the same application area as the large company. They are thus not excluded and shot out by the large company in the area where it has its competence and are performing its R&D.

The licensee's right to terminate without cause can be found in three other exclusive agreements as well. One of them has the same party relation and is construed as those with the two joint licenses commented above, and is thus very similar on the whole regarding this right of the licensee. The two others are however different. In one of these two the license will terminate but if the licensee continues to sell products for other indications in the licensed territory he shall be granted a nonexclusive license under the licensor's intellectual property and have a right to sublicense provided that royalty is paid. Here it is though oppositely the licensor that shall grant the licensee a nonexclusive license. The licensee's position is very advantageous but even the licensor, the intermediary firm, is in a not so bad situation. Since the license shall be nonexclusive the licensor can grant nonexclusive licenses to other companies. However a nonexclusive license may be regarded by a license speculator as not so interesting as an exclusive one, but this depends on the licensed object and the speculator's purpose with licensing in a certain knowledge and technology.

The third agreement states that the license of the licensee will terminate if the licensee decides to terminate the agreement without cause. The rights to the licensed object will be transferred to the licensor who also has the right to further commercialise the products in the territory of the former license. In this agreement the licensee, a company specialised in a specific area, has no rights left at all if he terminates it without cause and one major reason for this is that the licensor is a large multinational company. Such a construction is advantageous from the licensors point of view, since it will prevent the licensee from ending the agreement without cause only because of a minor reason. Now there shall be a major reason and a well-considered decision of the licensee before he terminates the agreement. The purpose of this construction seems thus to be primarily preventive.

Even in one nonexclusive agreement the licensee can terminate the license without cause. The result of such a termination is that he can independently develop products in the territory provided that a certain, in the agreement, defined patent does not cover these products. The consequence is thus that the licensee, a company, can be commercially active in the same area as the licensor, a non-profitable-corporation, after his termination, but he cannot commercialise products containing the licensed patent. Since the license is nonexclusive this is a natural consequence. The licensor has probably other licensees that are commercialising his patent in their respective products and then the terminating licensee shall have no such further right.

5.14.2.3 Consequences of termination due to material breach and insolvency or bankruptcy

The consequences of an early termination because of material breach and bankruptcy or insolvency can be regulated in the same clause or separately. In the agreements we have studied these termination circumstances are as a rule put together and have then normally the same outcome, regardless of which of them that the termination is based on. However as mentioned before it differs between the agreements whom of the parties that can terminate on

which circumstance(s). All these facts are thus going to affect how the termination will turn out.

Actually we found material breach clauses in all types of the studied agreements but in five agreements nothing is stated how the parties will handle the licenses and their related rights in such a situation. It seems though to be a tendency in the eight agreements, in which the parties have regulated how to handle the licenses in case of such a termination, that the exclusivity and any other nonexclusivity or semi exclusivity granted to the licensee will terminate, if the terminating party is the licensor. That the licenses terminate in case of the licensor's termination of the agreement is of course a natural consequence of the termination. The reason why the licensor have chosen to terminate the agreement is just to achieve this purpose. A clause with such content can be written like this:

> "… if Licensor terminates for Licensee's uncured breach … the rights and licenses granted to Licensee in Section … and … shall terminate …."

In addition the licensee has as a rule to give back important information of the licensor he has got access to via the agreement as well as transfer important information relating to development, to patents and patent filings and to regulatory filings and approvals that have been received by the licensee during the agreement period. These eight agreements are both exclusive with joint development and exclusive without such cooperation.

There is an exclusive agreement that shows a specificity regarding a mutual nonexclusive license that is granted for developments done during the agreement.[106] If it is the licensor that terminates the agreement because of a material breach caused by the licensee the mutual license will only remain for the licensor, which in this case is a company and probably of the same size as the licensee.

Since it is the licensor that is the party that in most of these agreements contribute with knowledge and technology it is clear that he will make sure that the licensee shall have no further right to develop and commercialise his input to the license relation. In all these eight agreements, except in one, the licensor is a research company of a smaller size. The exception is an agreement where the licensor is a large multinational company but there is no large difference in the licensor's rights in this agreement compared with the others. It can also be mentioned that the same result will occur in five of the eight agreements if the licensor terminates the agreement due to that the licensee is insolvent or bankrupt.

In the opposite situation, when the licensor has committed a material breach and it is the licensee who terminates the agreement, the situation is different. It can in general be said that the license of the licensee either remains or the licensor has to grant the licensee a license under his patents and under an eventual joint technology. The major part of these eight agreements has as their licensees a large multinational company and the rest are companies of a smaller size.

In one of the exclusive joint development agreements the licensor has to grant the licensee an exclusive, perpetual and irrevocable license in the territory where the licensee is active regarding the collaboration technique for all indications. The licensee is thus allowed to continue to develop and commercialise the collaboration technique in his area. Although the licensee has terminated the agreement it seems like the licensor still has the right to be active

[106] See section 5.10

in the licensed territory. When the licensor terminates the agreement of the same reason it is very clearly stated that the licensee's licenses shall terminate and that he has no further development and commercialisation rights of collaboration technology and products in the licensed territory. But when the licensee terminates nothing is mentioned regarding if the license of the licensor shall terminate as it is in the opposite situation. This commented clause is construed like this:

> "… if Licensee terminates for Licensor's uncured breach … Licensor is deemed to have automatically granted to Licensee an exclusive, fully-paid, irrevocable, sublicensable, perpetual license in the Licensee Territory under the Collaboration Technology for any and all purposes, provided that Licensor retains the ownership rights to Collaboration Technology throughout the world …."

Since the position of the licensor throughout the whole agreement is very strong compared to the licensee's a conclusion that the licensor's license continues might be possible. However it is quite surprising that the licensor has received such a control position since the licensor and the licensee in fact can be regarded as both licensee and licensor. They are each contributing with respective technology to be further developed in collaboration relating to the licensed object in the possession of the licensee. Obviously the licensor is transferring so much specific knowledge and competence that it gives him such control over the agreement. Another reason might also be that the license in fact is a cross-license agreement. In the pharmaceutical market both parties are companies active in different parts of the world.

Two other exclusive licenses without joint development are showing some specific characteristics regarding how the licensee's license and other related rights would be dealt with if he was the terminating party. In one the licensee is free to choose whether he wants to have his license uphold or not. This possibility is given both when the licensee's termination is based on a material breach or insolvency. Most possibly the licensee has this advantageous since he is a large multinational company and have been able to negotiate such a right with the licensor that is a small research company.

In the other one, improvements done by the licensee during the agreement and before the effective date of termination are regulated separately. When the licensee terminates the agreement he shall give the licensor an exclusive license to all improvements done by the licensee. Regulatory filings and approvals and patent applications related to any improvements shall also be transferred to the licensor.

In this situation it is the licensor that has the advantage and not surprisingly the licensor is a large multinational company. The licensee, a company concentrated in a specific area, has this obligation even in the opposite situation, when the licensor is the terminating party. The same result will occur whether the termination is based on a material breach or insolvency. Of course the licensor is eager to get all the improvements and related documents since he is the party that has contributed with knowledge and technology. For the licensor such a right is valuable to achieve and if he has a strong position, not said that the licensor then automatically has to be a large multinational company since a small research one can have lot of control depending on the situation, he should consider to bring it up to negotiation.

5.15 Special arrangements in favour of either party

As mentioned several times already, every agreement we have examined is particular. This is mainly because of two reasons. First of all, the license agreement gives the parties a large scope to create and modify regulations, as they find necessary and useful. Secondly, the specificity of pharmaceutical inventions and knowledge and the uncertainty connected with drug development makes it necessary to formulate and adapt the agreement to each specific licensing situation. The brief and short agreements are more or less alike; they all include the necessary regulations and not much else. The more detailed agreements often include regulations that are quite specific. We will here comment certain regulations that we find interesting and valuable for either of the parties to the agreement.

In one agreement the licensee shall every year provide the licensor with a list of products that might be of commercial interest, for a license, for the licensor. In this agreement both the licensor and the licensee are pharmaceutical companies, commercialising pharmaceutical products. They are though active in different parts of the world. If the licensor finds a product interesting the parties shall enter into good faith negotiations with the purpose to achieve a separate license agreement. This type of regulation can be very valuable for the licensor, being, as the licensee, a commercialising actor. It facilitates his chances to include more new products in his assortment. Such a regulation could of course, instead of products, comprise new inventions that the licensor could be interested in developing. It could also comprise both products and inventions.

In another agreement, which also has two commercialising actors as its parties, it is stated that the licensee shall consider the licensor as a potential licensee if he in the future wants to license the product to a third party. In this case the licensee will develop a pharmaceutical product based on patents and know-how owned by the licensor. Nevertheless the licensor is interested in selling the finished product in the future. Though the regulation is quite vague it still increases the licensor's chances to obtain a license to the product than these probably otherwise would have been. All such regulations are therefore important.

One type of regulation that might strengthen the position of the licensee and probably facilitate his development activities is the possibility to get access to assistance from the licensor. Such assistance is especially interesting in the beginning of the agreement, just when the licensee has taken over the project. In one agreement we have examined, the licensee has access to a certain number of hours of assistance during the first six months of the agreement. This assistance is at no cost. In another agreement the licensee had, at the time when entering the agreement, an option to also enter into a consultant arrangement with the licensor. The licensee did in this case choose to use this option. For this consultant possibility he pays an annual fee. These types of arrangements are not relevant when the parties perform R&D together, because in these cases such assistance is included in the program. But in other relations when the licensor possesses vital knowledge such an arrangement can be of great importance for the licensee.

Under section 5.10 it was mentioned that it is valuable for the licensee to have improvements made by the licensor regulated in the agreement. We also mentioned that a regulation stating an obligation or a possibility for the licensor to inform the licensee of any made improvements could be inserted in the agreement. A similar regulation could be inserted regarding new innovations. A clause stating that the inventing party shall inform the other party if he makes a new invention, that has some relation to the licensed invention, can be of

great importance for the other party. The clause could of course instead state that the inventing party “may” or “can inform the other party”, but such a regulation is for obvious reasons not that fortunate for the receiving party. The value of such a clause is difficult to estimate.

The mentioned information obligation can concern both inventions made by the licensor and the licensee, but they are probably more frequent in respect of inventions made by the licensor. This is due to the fact that the licensee is the party active in commercialisation and this often means that he constantly is in need of new inventions having potential of becoming a new pharmaceutical product. The licensor is more often a party just active in performing R&D. Whether the information clause only states a right for the receiving party to get informed or if it includes a right of first refusal to a license makes a great difference for this party. The best solution for him is to be free to choose whether he is interested in having a license under the relevant improvement or not, without being obliged to negotiate for such a license.

Several agreements have regulations that limit the licensor’s freedom to perform research. In such regulations the licensor agree not to perform any research connected with the licensed technology or within a certain field. For the licensee such regulations increase his possibility to be alone in the market with the specific product and it also increases his chances to have control over any improvements and over any further developments of the licensed object. In our examined agreements the licensee is a multinational pharmaceutical company when such a regulation is included. These companies are probably so strong and important actors that they can demand such regulations. Perhaps they are not interested in obtaining the license if such a regulation is not included in the agreement.

Regulations that strengthen the position of the licensor are also found in many agreements. In one agreement it is the licensor that shall decide what label the product literature and package shall have. In another the licensor decides in which countries the licensee must seek patent protection. The reason why the procedure to seek patent protection is regulated in detail in this agreement is probably due to the fact that the license concerns joint patents that is the result of previous joint R&D between the parties. The liens between the parties are in this case tights. But also in other agreements the licensor may affect the patent activities of the licensee. Such a possibility is of course important if the licensor has let the licensee handle patent issues.

A regulation also concerning patents, which can be very valuable for the licensee, was found in one agreement. The licensee can in this case require that the licensor shall seek additional patent protection if this is considered to be of significant importance for the maintenance of the protection of the licensor’s patents rights are intended to provide. If the licensor in such a case does not seek protection the licensee has the right to do it.

For a licensee in a nonexclusive license agreement it is always interesting to know how many other licensees there are to the same licensed object and it is also interesting not to be put in an unprofitable situation compared with other licensees. One of the nonexclusive license agreements we have examined encloses a “most favoured licensee” clause. Such a clause states that the licensor will not grant any rights containing the licensed rights under the terms more favourable that those granted to the licensee without giving the licensee the benefit thereof. For a licensee such a clause in a nonexclusive license agreement is very valuable. A clause stating an obligation for the licensor to regularly inform the licensee of the names of

the other licensees to the same object in the same area can also be very important for the licensee. Such an information duty for the licensor increases the possibilities for the licensee to terminate the license if he finds that the licensees are too many. A more valuable regulation would though of course be if the licensee could make the licensor agree to, in advance, fix a limit of the number of licensees and have this limit inserted in the agreements.

6. Conclusions

The agreements we have studied show that commercialisation of knowledge in the pharmaceutical industry can be performed in many different ways. We will now summarise what conclusions we have come to in our presentation and analyse and that we consider interesting.

As we have seen when studying the agreements these vary a lot, both regarding content and composition. Some of them are very detailed while others are briefer. It exists different opinions whether agreements should be regulating every conceivable situation in detail or just draw up the large lines. Some actors in the industry seem to think that it is better to create briefer agreements that establish the frames and the absolute restrictions, than to regulate everything in detail. Others consider though that it facilitates the relation between the parties if the agreement is clear and provides an unequivocal apprehension of how each specific situation shall be dealt with. All seem though to agree on that thorough and friendly negotiations are the best and most effective means to establish a good relation during the term of the agreement and to avoid disagreement and disputes.

In our opinion an agreement should be clear and unambiguous in its content and style. Three of the agreements we have examined are brief. These are read more easily and quickly the first time but we noticed that it in a more thorough study is difficult to understand and read out which rights the parties have and what the agreement actually regulates. In contrast of these three, six other agreements are very detailed and comprehensive. This made them difficult to read and to understand, but in return they normally comprise all the important regulations and can more or less be used as a book of reference.

We consider a detailed agreement in general to be preferable to a briefer one. An agreement must at least comprehend the obligations and rights of each party and other regulations that are important for the relation between the parties. In some cases detailed regulations may impede the collaboration between the parties, because the relation is too controlled and restricted. Even if the obligations and rights of each party must be comprised in the agreement, it may be better not to regulate the actual performance of these obligations and rights in full detail. A more flexible regulation can therefore in some parts be better. A solution, in the cases the parties want to more thoroughly decide how certain activities shall be performed by either of them, could be to establish a committee. This committee could then be a forum for decisions regarding how the performance of the parties' obligations and rights shall be done.

Since smaller research companies and researcher in the academia have become important suppliers of new knowledge and innovations for the larger pharmaceutical companies, it is often such actors that are the licensors in the license construction. This party constellation is also the case in most of the agreements we have studied. In as many as nine of the 13 examined agreements the licensor is a small company or an actor linked to the academia, while the licensee is an actor of larger size. In five agreements the licensee is even a

multinational pharmaceutical company. As we have mentioned several times throughout the essay, the fact that the licensor is of a smaller size does not have to imply that he therefore becomes inferior in the contractual relation. This is due to the licensor's possession of rights to knowledge that the licensees are in need of, in order to be and remain competitive in the market.

Even if the information furnished above indicates that small and large parties are equal, we are of the opinion that some agreements show that the licensee, being a large party, has obtained a more advantageous position in the agreement than he would have if the counterpart was of an equal size. Regulations that show signs of this inequality are rights of termination and its consequences, the decision rights in a joint development program and the licensor's possibilities to affect and control the performance of the licensee.

The license as such is an extremely flexible instrument that can be varied in many different ways. Two parties negotiating for a license can choose among one of the three types of licenses, exclusive, sole and nonexclusive, or combine these in different areas. The parties also decide the territory, medical field of application and the activities to be included in the license. The exclusive license is the most frequently used when the licensing is being made in the beginning of the development process of a pharmaceutical. This choice is understandable since it probably is best for both parties in such a situation. Since the licensee takes all the risks he wants to obtain the exclusive right to the licensed object in order to be able to benefit from it, he is then also willing to pay more for the license.

Even if an exclusive license may have advantages in many situations this does not have to mean that it is inferior to the other types of licenses in all cases. The nonexclusive can be more appropriate when the development is completed and the license only relates to sales and marketing activities. When a licensed object has several fields of application it can also be suitable, even though the license in this case instead can be made exclusive in the particular field of application.

The possibility for the licensee to sublicense the rights granted in the agreement to third parties may be of importance. As we have seen such a possibility seems to be common, at least this is what we found in the studied agreements. Though it always, also when the rights has been sublicensed, is the licensee that is responsible for the fulfilment of the agreement in relation to the licensor, sublicensing could be risky for the licensor. It is always best for the licensor to have control over the parties that have access to his property and knowledge. A sublicensed actor may act in a way that can give the licensor or his property a bad reputation. We therefore consider that the right to sublicense should be combined with a requirement of a prior approval from the licensor when a sublicense is granted to a party that is not an affiliate or a subsidiary of the licensee. Irrespective of which party the sublicense is granted to, we consider it important for the licensor to be informed.

We have found that in the agreements the parties perform R&D in cooperation the license in most cases seems to be divided in two parts, one concerning the performance of joint development and one concerning the future commercialisation. The R&D work the parties perform in these cases has as its base an innovation or technique supplied by the licensor and a program and a committee are established for the joint activities. All these agreements are established in a very early phase of the development process when the outcome of the R&D still is uncertain. Both for a licensee and a licensor the joint development can be valuable. In the agreements we have studied the licensee appears to be more dependent on the knowledge

and experience the licensor possesses, than he appears to be in agreements without joint development. The licensor appears to be more interested in the results of the development than in many other agreements. In some agreements he is also a commercialising actor while he in others can benefit from the outcome in other projects and research areas he is involved in.

When the parties perform development together it is important that the research program can be modified during the term of the program. This is necessary in order to reach the best possible result since research in its nature is unpredictable. The information duty in between the parties is also very important when joint research is being performed. This is a prerequisite for each party in order to be able to comply with his obligations and tasks under the program. The parties are very dependent on each other and therefore information is necessary to continuously know what the other party have done, does and will do. Additionally it is of course also vital that the parties can terminate the R&D collaboration if it has lost its purpose or if one of the parties has failed to comply with his obligations.

Having access to the other party's improvements of the licensed object can be vital, but such an access is only interesting and relevant if both parties will continue to perform research on the object. Regardless if either party shall have a right to the other's improvements, the most important is that the parties during the negotiations have discussed these issues and that the agreement is clear on this point so that no misunderstandings will arise. In most of the exclusive license agreements we have studied improvements made by the licensor during the term of the agreement are included in the object of the license. Such improvements are hence automatically licensed and made accessible to the licensee. This regulation can of course affect the licensee's chance to use the licensed rights in the best possible and profitable way.

If the improvements of the licensor are not included in the object and neither regulated separately in a special clause, it may still be of importance to regulate improvements in the agreement. A regulation stating that the licensor shall notify the licensee of any made improvements or inventions related to the licensed object can, for example, be useful for the licensee.

The licensor's access to the licensee's eventual improvements has above all relevance in the agreements with a nonexclusive license. In these cases the licensor often wants to have access to such improvements in order to be able to transfer these to his other licensee's. Therefore the licensor should see to that such a clause is inserted in the agreement. The licensor can also have an interest in access to the licensee's improvements when the license is exclusive or sole. This is primarily the case when the licensor somehow active in R&D or/and commercialisation related with the licensed object.

The responsibility of patents and patents applications, but also of regulatory filings and approvals, should be handled by the party that is the most suitable and has the best possibilities to take care of such actions and assets. The same party shall also have the ownership of these assets. The most important in these situations is that the other party is fully and adequately informed of the responsible party's actions. In some cases this information is necessary in order to practise the rights granted in the agreement, while it in others has a more preventative aim as a means not to lose any rights connected with the agreement. In the situations when one of the parties is responsible it is also important that the other party has an opportunity to take over this responsibility if the other fails in performing his obligations. If it is the licensee that has failed to comply with his obligations some sort of sanction is

appropriate. Such a sanction could be the termination of the license or to make it nonexclusive or sole in respect of the particular patent or product, either totally or just in the concerned country.

When commercialising with knowledge it is more important than in other commercial transactions for the party that grants the use of the knowledge to have a possibility to supervise and evaluate how his knowledge is developed and taken care of by the receiving party. The most important instrument in the license agreement for controlling this commercialisation is performance obligations. Through this instrument one party can evaluate if the other has made an adequate performance. To clearly regulate what is expected of the party having the performance obligation is best for both parties. This gives the performing party a clear picture of his obligations and what is expected of him. And for the other party such a regulation makes it easier for him to know if the agreement is being performed as anticipated.

The performance obligations can be in respect of both the licensee and the licensor, but these regulate for natural reasons more often the performance of the licensee since he is the main performer. Performance clauses can though regulate the performance of the licensor as well. This is the case when the licensor is involved in joint development with the licensee or when there are other activities that the licensor shall perform that are of importance for the licensee and his utilisation of the license. Such an activity can for example be the supply of compounds or assistance.

For the licensee flexible or no performance obligations are preferable to detailed ones, since he then has a larger scope of freedom to decide when and how he shall use and develop the licensed object. The licensor should though absolutely see to that the agreement states some sort of control function regarding the licensee's development and utilisation of the licensed object. A well-considered and formulated performance clause can be a very effective means for the licensor to evaluate and control the activities of the licensee. A too detailed and strict performance obligation is however probably not in favour of either party. Since the development of pharmaceutical products often is connected with much uncertainty and risks, it is important that time limits in a performance clause can be adapted if needed.

We believe that it is most appropriate for the licensor to have a general performance obligation as a basis. Such an obligation shall stipulate that the licensee shall use best reasonable efforts when developing and commercialising the object of the license. Even if such an obligation is vague it can be effective and valuable for the licensor, especially if it is combined with some sort of sanction. We consider though that the general performance obligation should be accompanied with time limits regarding certain activities of the licensee within which the licensee must act. Such activities should at least be the filing of marketing approval and the launching of the product. If the licensee fails to comply with the obligation there should be a possibility for the licensor to activate a sanction.

It can be important for the parties of a license agreement to be able to terminate it in advance. Such possibilities should be regulated in the agreement, in order to prevent disputes when such events occur. Common reasons for early termination are material breach, insolvency or bankruptcy and without cause. The parties should also consider what effects an early termination shall have regarding the licensed object and the relation between the parties. These effects can vary depending on which circumstance the termination is based on.

We end this essay with a short list over some points that we find important to have in mind when a license agreement is going to be established between two parties in the pharmaceutical industry.

- The agreement should favour and create opportunities for a good dialogue between the parties during the term of the agreement. A committee can be a forum for such a dialogue, since the parties then meet at regular intervals.
- The obligations and rights of each party should be distinctly expressed in the agreement.
- The agreement should be clear. It should be easy to understand what the agreement signifies in different situations. Situations when this is particularly important are for example in case of infringement, disputes, adverse events and termination. The agreement should also clearly state if a party shall have access to the other party's improvements and which of the parties that shall obtain ownership to rights connected with the license.
- Both parties should have regular information regarding the other party's activities under the agreement.
- The agreement should stipulate means for the parties to evaluate and control the other party's performance under the agreement. The licensee should have an obligation to perform the development and commercialisation of the licensed rights in compliance with predetermined requirements. A failure to comply with the obligations should result in some sort of sanction.
- A possibility of early termination for the parties and the effects of such termination should be included in the agreement.

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7.6 Answerers to questionnaire

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Urban Paulsson	Vitrolife AB
Jan G Smith	Abigo AB
Kjell Stenberg	AstraZeneca AB
Anders Vedin	Chalmers

8. Appendix

Frågeformulär (Original version)

Vänligen fyll i svar på frågorna nedan i den mån ni kan. Svaren får gärna vara utförliga och långa. Är det någonting ni tycker att vi missat att fråga om får ni gärna komplettera.

Fördelning av utvecklingsprocessen av läkemedel

1. På vilka grunder väljer man att lägga delar av utvecklingsprocessen av läkemedel internt, inom företaget, eller externt, hos andra företag, forskare, institutioner?
   Ekonomiska/strategiska/praktiska grunder?
   Vilka delar i utvecklingsprocessen av ett läkemedel läggs vanligtvis internt/externt?

Externt

2. Vilka former av externa relationer förekommer genom avtal?
   Kontraktuella/Informella
   Hur viktigt är externa relationer vid utveckling av läkemedel och i vilka faser är de externa relationerna viktigast?
3. Vad styr valet av extern avtalspart?
   Vid FoU-samarbete/licens
4. Hur ser en avtalsprocess ut i allmänhet?
   Vid FoU samarbete/licens
   Vilka olika tidsperioder/faser etc. (föravtal?)
   Vilka personer deltar i de olika faserna i avtalsprocessen och varierar detta beroende på när i ett läkemedels livscykel avtalsprocessen sker? (management, jurist, genomförare (ex forskare))
   Hanteras/regleras vanligtvis hela relationen parterna emellan i ett avtal (eller förekommer underavtal?)?
5. Det första avtalsutkastet (draft), utarbetas det av parterna ihop eller av en av parterna? Om av en, i så fall vem? Spelar detta upplägg någon roll för framtida drafts?
6. Vad är målet/syftet vid utformandet av FoU-/licensavtal?
   Kan dessa avtal ses som styrmedel/verktyg för att uppnå en kontrollsituation? (kontroll över kunskap)
   Är kontrollsituationen som skapas genom avtalen viktig?
   Försöker man skapa en så optimal situation som möjligt för båda parter genom avtalet?
7. Hur vanligt är det med omförhandling av avtal?
   Vid FoU-/licensavtal
   Orsak till omförhandling
8. Informationsskyldighet föreligger för parterna i många delar i avtalen.
   Hur kan man kontrollera att informationsskyldighet mellan parterna följs? Är det vanligt att avtal sägs upp på grund av att det brister i informationsskyldighetsplikten?
9. Är det svårt att komma överens om vem som ska ha äganderätt till immateriella rättigheter som tas fram inom ramen för avtalet?
   Finns någon praxis på detta område?
10. Vilken betydelse har de performance-klausuler som oftast återfinns i avtal, där licenstagaren kan vara skyldig att prestera olika saker vid olika tidpunkter eller som i allmänna ordalag anger att licenstagaren ska lägga ner lika mycket arbete på inlicensierat objekt som på eget?
11. Vilken betydelse har olika former av garantier (”warranties”) som brukar återfinnas i licensavtal?

12. Anser ni det viktigt att ha kontroll över att det finns en informationsplikt om eventuella skadliga effekter av en substans/läkemedel i ett licensavtal?
    Hur vanlig är det att sådana klausuler skrivs?
13. Kan man säga att det uppkommit en slags standardisering av licensavtal att det utvecklats en praxis?
    I vilka delar av avtalen har detta i så fall skett?

Internt

14. Om utvecklingen av ett läkemedel istället sköts internt – hur styr man denna utveckling?
    Hur sker kontroll över processen och styrning av kommersiella lösningar?
15. Finns det generellt några steg i utvecklingsprocessen av ett läkemedel som anses vara bäst att sköta internt och i så fall varför?

Avtalsobjekt vid licensiering

16. Finns det något problem i att ha kunskap/immaterialrättigheter som avtalsobjekt?
    Är man noga med att under avtalsförhandlingarna precisera vad som är avtalsobjekt?

Konflikter

17. Hur viktigt att det är att förebygga eventuella konfliktsituationer i ett avtal, dvs. hur konflikter ska lösas eller vilka typer av konflikter som kan uppstå och hur konflikter med avtalspart/tredje man kan undvikas?

Nätverk

18. Förekommer samarbete genom nätverk inom läkemedelsbranschen?
    Vad är positivt med nätverkskonstuktioner?
    Finns det både formella och informella kontakter i ett nätverk?

Questionnaire (English version)

Please fill in the answers to the questions below to the extent you find possible. The answers may gladly be thorough and long. If there is anything else you think that we have missed to ask about, you are welcome to complete.

Distribution of the development process of pharmaceuticals

1. For which reasons do you choose to perform parts of the development process of pharmaceuticals internally, within the company, or externally, at other companies, researchers or institutions?
   Economical/strategic/practical reasons?
   Which parts of the development process of a pharmaceutical are most usually performed internally/externally?

External aspects

2. Which forms of external relations exist through agreements?
   Contractual/Informal
   How important are external relations when pharmaceuticals are being developed and in which phases are these external relations most important?
3. What governs the choice of an agreement partner?
   In an R&D cooperation/in a licensing situation
4. Which are the general features of the negotiation process?
   In an R&D cooperation/in a licensing situation
   Which different periods/phases are there?
   Which persons participate in the different phases of the negotiation process and does this vary depending on when in the life cycle of a pharmaceutical the negotiation is taking place? (Management, jurists, researchers)
   Is the whole relation between the parties in general treated/regulated in one agreement?
5. Do both parties develop the first draft together or just one party? If only by one of them, by whom? Does this make any difference for future drafts?
6. What is the main purpose when R&D cooperation/license agreements are being established?
   Can these agreements be seen as tools for achieving a control position (control over knowledge)
   Is the control position that is created though the agreements important?
   Do the parties try to create the most optimal situation possible for both parties through the agreement?
7. How common are renegotiations of the agreements?
   R&D cooperation/license agreement
   The causes for such renegotiations
8. The parties have information duty obligations in many parts of the agreements.
   How do you control that the information duty between the parties is being followed? Is it common that agreements are terminated due to failure to meet up to the information duty obligation?
9. Is it difficult to agree on which party that shall obtain the ownership in intellectual property rights developed within the agreement?
   Is there any practice developed regarding such issues?
10. Which significance does the “performance clauses” have that usually can be found in agreements, and which oblige the licensee to a certain performance at certain periods or

which in general terms state that the licensee shall devote the same efforts to an object that has been licensed in as on an object of his own?

11. Which significance does the different types of ”warranties” have that normally can be found in license agreements?
12. Do you consider it important to have control over the existence of an information duty regarding adverse events of a substance/pharmaceutical in a license agreement?
    Are such clauses common?
13. Has some kind of standardisation of license agreements been created, a practice been developed?
    If this is the case, in which parts of the agreement has this happened?

Internal aspects

14. If the development of a pharmaceutical is handled in-house – how is this development then governed?
    How is the process and the governance of commercial solutions controlled?
15. Are there any general phases in the development process of a pharmaceutical that is considered to be best performed in-house and if this is the case, why?

The object of a license agreement

16. Are there any problems with having knowledge/intellectual property rights as the object of an agreement?
    Do the actors consider it important to precise the object of the agreement in detail during the negotiations?

Conflicts

17. How important is it to prevent eventual conflict situations in an agreement, i.e. how conflicts shall be solved or which kind of conflicts that may arise and how conflicts with a counterpart/third party can be avoided?

Networks

18. Is there any cooperation through networks within the pharmaceutical industry?
    What is positive with the network construction?
    Are there both formal and informal networks?