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# Are the bio-health related patents delaying research? A study of relevant legislation, facts and the research conditions in the United States

Graduate thesis
20 points

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# Summary

When initiating the research for my graduate paper I had a rather straightforward intent in mind. It was to determine if the research being conducted in the bio-health related field was negatively affected by the patent system. If the research was delayed by the patent system I wanted to apprehend why.

I came to the conclusion that over the years the sphere where the exchange of intellectual property is taking place is very much different than it was just 20 years ago. This rapid evolution is linked to a phenomenon, which is referred to as “the biotech revolution” or the “the genetics revolution”. It is the question of dynamic technologies and scientific fields where progress has been continuous over the last two decades. The patent system has contributed, through that it has stimulated the will to innovate and invest in genetic and biomedical research. The idea what constitutes a patentable subject matter has also changed considerably. The Intellectual Property system is fairly adaptable, which is indicated by patent office practice.

The bio-health related field of research and development is ruled by a commercial business climate. There is big interest in investing as well as initiating new research forums. It is obvious even to the outside world that this is a market generating profit. An important part of the market is concentrated to the United States.

In 1980 the US Congress passed the Bayh-Dole Act. It is a piece of legislation that allows research universities and government to be granted patents for their inventions. This has resulted in a change in interest for the universities. They are now taking part in the commercial exchange of research information in a different way than they did before. It has become more complicated to conclude license agreements, due to the new role of the universities and the lack of understanding between different institutions. Problems regarding license agreements may also arise within a university, especially between the scientists and the professional lawyers responsible for the license contracts. All in all the Bayh-Dole Act the Bayh-Dole still is said to have had a very positive effect and has contributed to technology transfer to the benefit of the general public.

Another problem, particularly within the field of human genetics is an increased level of secrecy among scientists. Friendly sharing among colleagues is less common, since it is important to keep discoveries secret when applying for a patent.

# Abbreviations

| | |
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| DBF | Dedicated biotechnology firm |
| DNA | deoxyribonucleic acid |
| EPO | European Patent Office |
| ICESCR | International Covenant on Economic, Social and Cultural Rights |
| IPO | Initial Public Offering |
| JPO | Japan Patent Office |
| HUGO | Human Genome Organisation |
| MTA | Material Transfer Agreement |
| OECD | Organisation for Economic Co-operation and Development |
| R&D | Research and Development |
| RNA | Ribonucleic Acid |
| TRIPs | Trade Related Intellectual Property Rights |
| UDHR | Universal Declaration of Human Rights |
| UNESCO | United Nations Educational, Scientific and Cultural Organisation |
| UK | United Kingdom |
| US | United States |
| USPTO | United States Patent and Trademark Office |

# 1 Introduction

## 1.1 Background

The adjective “patent” means open. This title derives from “letters patent” or open letters, which in fact were official documents where certain privileges, such as ranks, titles or rights were conferred to the nobles by the sovereign grantor. The openness was linked to the fact that they were publicly announced and endowed with a seal of the sovereign grantor. The letter represented the right or rank given to its recipient.[1] Still today, a part of the process when being awarded a patent is the process of disclosure. A procedure, through which, the invention is made official to the general public.[2]

The patent system is intended to function as an incentive to innovate and invest in research projects. It is a system developed to benefit two interests. First of all the rights of the inventor or the owner of the invention is safeguarded. The holder of the patent is protected from others using or economically exploiting the invention without permission. The general public on the other hand, is entitled to enjoy the inventions through a purchase or by enjoying the simple pleasure of learning about them. The idea is that the patent system should function as a contract, which allows the inventor to enjoy the benefits of patent protection, while providing inventions and scientific results, which are of enough interest and use to the general public.

The area of research I examine in this paper is that of biotechnology and human health related industries. These are fields of research, where progress is rapid and continuously accelerating. I want to explore issues and problems that are brought by the patent institute to those particular fields. Biotechnology is complex and new products and procedures are developed from several different underlying technologies. Today scientists are skilled in how to sequence genes, identify their functions and mutations. The scientists also know how to create systems to selectively express, regulate or silence genes. Such knowledge is valuable and can constitute an important power-tool, due to its commercial and social value. The rapid evolution has been named “the genomic revolution”. The different related technologies contribute to a development in the life sciences and bring enormous possibilities of improving human-health. The progress in the biotechnology field is testing the boundaries of the patent criteria and system. Debates have been lively on the patenting of genetic and biological material and whether they should really constitute patentable subject matter. The

[1] Shiva V, *Protect or plunder? Understanding Intellectual Property Rights*, 2001 London, Zed Books, p. 12.
[2] Murashigue K.H., *Overview of Potential Intellectual Property Protection for Biotechnology* http://www.piercelaw.edu/risk/vol5/spring/murashig.htm, 26/3/03.

adaptability of the existing patent system has helped to promote the evolvement of a new and important industry.[3]

## 1.2 Object and purpose

Last year I wrote a paper in which I examined the boundaries of the patent criteria as regards the patenting of DNA fragments and in particularly the human genome. I also explored the issues around the patenting of genetic material. In my research for this paper I found signs that indicated that these patents could be of trouble to the procedure of conducting research in the field of biotechnology and biomedicine. The problems were specifically linked to the many patents that were being issued on DNA fragments and the methods for isolating or purifying the DNA fragments. It was suggested that the patents, which were granted, were either too broad or too fragmentary. In both cases this could lead to a difficulty in gaining access to the patented subject matter for researchers that were in need of that particular DNA fragment as a part of their research. I also discovered indications of an increased secrecy among scientists and was curious to see, whether the withholding of data between fellow scientists was linked to the DNA patents, or not. As a consequence, I was determined to continue the research and try to explore, whether my notions were founded. The interest of the effects that the patent system may have on the conducting of research in the bio-health related field was also further developed by stories and experiences shared to me by PhD-students and a research assistant. I also came across some statistics clearly stating an enormous increase in patent applications for genetic material and the application of such material. The numbers reported seemed high and I wondered how all these patents affect the research in the biotechnology and health-related fields.

Numbers provided by the Organisation for Economic Co-operation and Development (OECD), clearly indicates a revolution in biotechnology and the genetics industry. From 1990 to 2000, the numbers of patents that were granted in biotechnology at the United States Patent Office (USPTO) rose 15% a year. At the European Patent Office the corresponding number was 10,5%. The numbers should be estimated against a 5% a year increase in patents. A branch of the biotechnology patents is the “genetic inventions”. The USPTO, EPO and also the Japan Patent Office (JPO) reveal a dramatic increase in the number of gene patents that are being issued since the second half of the 1990’s. In 2001 over 5000 DNA patents were granted by the USPTO and the EPO reports that it has issued several thousands for genetic inventions.[4]

[3] Ibid. p. 7.
[4] The OECD expert Workshop January 24-25 2002 on “Genetic Inventions Intellectual Property Rights and Licensing, http://www.oecd.org/dataoecd/42/21/2491084.pdf, 5/1/04, p. 8.

The commercial influence on the bio-health research creates a scenario where both private and public researchers take the opportunity to apply for patent protection. They hope that their inventions may be of commercial application and value. In keeping in mind this reality and this particular field of research I have chosen a few key issues, which I explore and discuss in my paper. One issue is that the exchange of ideas seems to be running less smoothly, due to the fact that the patent criteria is expanded in order for it to be in tune with progress in research. There are patents, which are claimed to be overly broad or too fragmentary.

I have also chosen to examine the infrastructure and the different institutions taking part in the exchange of information and research results through licensing, which ultimately lead to new commercial products. I have further turned to different sources to see how the cooperation and exchange of ideas is flowing between institutions like research universities and biotech firms or pharmaceutical companies. In the process of examining the different actors within the bio-health related field I discovered also that problems could arise within an institution. The institution in question could be a university conducting research as well as biotech firm or a pharmaceutical company. The disturbances within an institution are often the result of conflicting interests of the different employees or executives. My intent was to estimate how the legislative changes, such as the enactment of the Bayh-Dole Act[5], could have affected the institutional infrastructure. I have also been interested in seeing the effects that this piece of legislation may have had upon the "research climate", that is to say the environment in which the scientists operate. I have estimated to provide a picture of the said environment, since I think it is important to understand the background to come to grips with from where patterns originate. In my paper there is also a headline defining some of the terminology, which I have used to clarify the field of research that I have limited myself to refer to.

## 1.3 Delimitations

I have decided not to talk about the process of applying for patents and the difficulties and harmonisation issues belonging to that particular topic. My interest lies more in the difficulties associated with the Bayh-Dole Act and expanded patent criteria in biotechnology. I concentrate on examining whether the patents have a delaying and negative influence on research and development in the field of bio-health related research, or not.

In this paper I examine the infrastructure between the different research institutions in the United States (US). In my opinion this country and its influential involvement in bio-health constitutes a splendid and clear example of the commercial side of research and development. The view upon property, tangible as well as intangible, is clearly representative for a

[5] More below under headline 3.

market economy. The bio-health industries do not know borders and this is expressed in a common universal market. The infrastructure that I describe is to large extents the one representative for the US, but it is a structure, which affects in a much larger area.

## 1.4 Method and material

I initiated my work by exploring different Internet pages treating the questions and issues that were of interest to me. I also explored web pages belonging to different organisations, such as the UNESCO, OECD and WTO. Subsequently I turned to web pages belonging to the European Patent Office (EPO) and the United States Patent and Trademark Office USPTO. I turned to literature as well, often with intent to compare with information from the Internet and different articles found on the Internet.

To put the research society of the US in perspective I have used international, regional as well as national regulation and legislation. I have used legislation in my illustration of the research situation to a limited extent, since it is rather the effects of a structure of cooperation that has captured my interest. The legislation I use is intended to clarify the patentable subject matter and what kind of institutions that can receive patent protection.

I have to some extent relied on the results of two different workshops, since they have treated in expert discussion the questions corresponding with the subject for this paper.

The practice by national and regional courts is intended to clarify the extension of what constitutes patentable subject matter and also to illustrate how the development towards the existing scope of the patent criteria is possible.

In the process of research I have spoken to people around me involved in research at the Lund University and it has been interesting to listen to their knowledge and experience as regards the patent system.

## 1.5 Outline

To be able to clearly understand the subject I begin with a chapter, where I try to determine the developments that have led to the research situation in which we find ourselves today. I examine legislative and institutional changes. I also examine the patentable subject matter and how it may contribute to our current research climate. Under this chapter I also illustrate the level of international cooperation regarding patents that obliges the US.

In chapter 3 I look upon the function of the patent system and foremost the positive and negative effects it has upon the pace of Research and

development (R&D). Chapter 4 is dedicated to a brief explanation of the field of research with which I concern myself.

The following chapter is treating the important questions regarding the structure of research exchange. I bring up issues and problems related with this structure and the factors that exchange of research information depends on. In the succeeding chapter I describe the different institutions involved in doing research and bringing pharmaceutical products to the market. In this process I also reveal problems in collaboration between the different players in the field.

I have dedicated chapter 7 to other issues that are related to our current research society and which might delay research. Under the headline "research climate" I reveal the background and reality in which the scientists and researchers operate. I also discuss issues related to patents on genetic material. A concluding discussion is to be found under chapter 8.

# 2 Changes in law and an expanded patentable subject matter

## 2.1 General remarks

The sphere of intellectual property exchange is expanding in terms of participants and object of exchange within the field of biotechnology and the area of "life-sciences". As a result the proprietary exchange can be said to be more diverse. Due to this development certain problems have arisen in the exchange of biomedical information. Regarding the participants they are more numerous in terms of different types of institutions as well as the actual number being offered patent protection for their inventions. Now "…academic and non-profit institutions have established technology transfer offices to patent faculty inventions and to market them to commercial firms".[6] Institutions, which earlier used to let their discoveries be freely available to the public and the research society, are nowadays filing patent applications for their work.[7] This development is the result of amongst other things, a policy shift regarding Intellectual Property introduced by the US Bayh-Dole Act from 1980 and subsequent amendments enacted by the Congress.[8]

Over the years the meaning of what constitutes a patentable subject matter has changed. The matter appears to be the same with the different institutions filing for patent. The universities and other federal institutions often conduct the initial research in the linked research chain leading to early-stage discoveries, since this type of research is granted patent protection. The object of exchange, that is to say a patentable subject matter, nowadays is much different from what it was a few decades ago.[9]

The patent system appears to be rather adaptive and welcoming towards new developments in science and different technologies. This is suggested by the practice of the patent offices and patent criteria that are interpreted rather widely. The "Diamond v. Chakrabarty case" is often mentioned as the starting point for these changes.[10] The decision taken by the United States

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[6] Eisenberg R.S, *Bargaining over the transfer of proprietary research tools: is this market failing or emerging?* As in *Expanding the Boundaries of Intellectual Property: innovation Policy for the Knowledge Society*, edited by R. Dreyfuss, D.L Zimmerman and H. First, 2001 New York, Oxford University, pp. 226.
[7] Ibid. p. 226.
[8] 35 U.S.C. §§ 200-211
[9] Ibid. p. 226.
[10] The background to the "Diamond v. Chakrabarty case", 447 U.S. LEXIS 112 (1980), is that a man named Chakrabarty filed a patent application to the United States Patent office for a new form of bacterium obtained by genetic alteration. The controversy lies in that the

Supreme Court has proven to be highly important and has stimulated the research community all over the world to file patents on genetic material. Chakrabarty was awarded a patent for a bacterium, which was genetically engineered to consume oil spill. The court chose to see the bacterium as a new life form and not as one naturally occurring form of life in nature. The "Chakrabarty case" certainly was groundbreaking. Representatives of the biotech industry world argued that patents should be granted for genes, proteins and other materials, which possibly could generate profit.[11]

The Human Genome Project (HUGO-project) is a second factor that may have contributed to an increased number of patent applications for genetic material. It was established in the 1990s and terminated in 2003 and the main goal with this research programme was to map and decode the human genome.[12]

A third factor that may, according to some, have led to a less restrictive interpretation of the patent criteria and what constitutes a patentable subject matter, is the TRIPs Agreement. The patent criteria is described in article 27.1 of the TRIPs Agreement and the patenting of living material is justified according to article 27.5.3(b). It is claimed by Vandana Shiva, the author of the book "Protect or Plunder? Understanding Intellectual Property Rights", that it was different multinational companies (MNCs), who used the United States to enforce the TRIPs. In the process these powerful companies also demanded a removal of all limits on patentability.[13]

## 2.2 Patentable subject matter in biotechnology and genetics

To determine whether living material such as proteins, DNA- sequences, different microorganisms and animals may constitute patentable subject matter, it is necessary to turn to relevant laws as well as practice. The criteria for obtaining a patent are quite similar all over the world. A patent protection is sought to protect an invention, which may be a process, code or device.[14] To be granted with patent protection, the discovery has to be a patentable subject matter and fulfil the three basic criteria of novelty,

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Supreme Court in its decision considered the bacterium as a new life form and not a mere naturally occurring form of life. It was the result of "human ingenuity and research".

[11] Sagoff M, *Patented Genes: An Ethical Appraisal*, Issues in Science and Technology Online, spring 1998, http://www.nap.edu/issues/14:3sagoff.htm, 26/3/03 and Diamond v. Chakrabarty, 447 U.S. LEXIS 112 (1980).

[12] *Le décryptage du genome humain est officiellement terminé*, Le Monde, 14/4/03, http://www.lemonde.fr/article/0,5987,3244--316866-,00.html, 15/4/03.

[13] *Protect or Plunder? Understanding Intellectual Property Rights*, pp. 95-97.

[14] Hasson A. I, *Patenting Biotechnology: Inherent Limits*, 2002 B.C. Intellectual Property and Technology, http://infoeagle.bc.edu/bc_org/avp/law/st_org/iptf/commentary/content/2002041901.h…, 3/11/03.

inventive step and industrial applicability.[15] In the US, the criteria for obtaining a patent are differently expressed and they are concluded as novelty, non-obviousness and utility.[16] The opposition division in the Relaxin case presents a more informative conclusion of the patent criteria. "An invention must have technical character, i.e. must constitute an industrially applicable technical solution to a technical problem, and also be reproducible without undue burden. A product must furthermore be novel in the sense of having had no previously recognised existence and must in addition be inventive."[17] As an additional criterion it also has to be sufficiently described so that it can be enabled.[18] The invention is made public through the patent application being filed with the US Patent and Trademark Office (USPTO). The application is required to "...contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."[19]

Biotechnology patens in the US are usually patentable as in the article for manufacture or composition of matter categories while patents on DNA, proteins, antibodies, transgenic microorganisms, viruses, animals and plants are also possible.[20] When it comes to DNA and RNA they are patentable as chemical compounds.[21] To be more specific in what constitutes patentable subject matter in the US: the application has to relate to "a composition of matter, a process, a machine, or an article of manufacture."[22] More specifically, when the patent application concerns the field of biotechnology a patentable subject matter can be proteins, DNA molecules, cell lines, mice, antibodies, methods of treatment, methods of recombinant production and so on. A patent application can also concern a method of diagnosis, methods to conduct electrophoresis, chromatographic columns and assay devices, to mention a few more examples. All of the abovementioned are "statutory subject matter", according to Kate H. Murashige author of the article "Overview of Potential Property Protection for Biotechnology".[23] It is also said that patents can be issued on genes and gene sequences, but in

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[15] See for instance art. 27(1) of the TRIPS-agreement from 1994 and art. 3 of the dir. 98/44/EC

[16] Westerlund L, *Biotech patents: Equivalency and Exclusions under European and US Patent law*, New York 2002, p. 7, footnote 50.

[17] Ibid. p. 2.

[18] *Patenting Biotechnology: Inherent Limits*.

[19] Murashige K.H, *Overview of Potential Intellectual Property Protection for Biotechnology*, http://www.pierclaw.edu/risk/vol5/spring /murashig.htm, 26/3/03 and 35 U.S.C. Sec. 112, [[paragraph]] 1.

[20] Ibid. and Title 35 United States Code § 101 (1994 & Supp. II 1996).

[21] *Biotech patents: Equivalency and Exclusions under European and US Patent law.* p. 7 footnote 47.

[22] http://www.piercelaw.edu/risk/vol5/spring/murashig.htm, 26/3/03 and 35 U.S.C. Sec 101

[23] http://www.percelaw.edu/risk/vol5/spring/murashig.htm, 26/3/03. In the footnote 7 in her article, she mentions that all of the above mentioned components are not patentable subject matter according to the patent legislation in every country.

reality when we talk about issuing patents on genes it is actually genes, cDNA sequences that we really mean.[24]

Nowadays, the boundaries for what constitutes a patentable subject matter have been expanded, but there are still limits and I will shortly mention where they are drawn. Excluded from patent protection are still laws of nature, mathematical and scientific formulas, abstract ideas, naturally occurring objects and human life.[25]

The conditions for patent protection above mentioned are to be applied to results achieved in a rapidly expanding and accelerating biotech and genetic industry and naturally it is important for the traditional concepts to be interpreted to be in tune with the research society.

### 2.2.1 The utility criterion

When applying for patent on genetic material in the US the question if the subject matter is patentable or not is to a high degree resting on whether or not it is viewed as useful.[26] The requirement that an invention has to be useful when applied to biotechnology does not necessary mean that it has to be commercially useful. It must, however represent a measurable benefit of some sort. It is not enough to produce something that is an object in scientific research to be granted a patent. The written description and the enablement requirements are often enough, to determine whether an invention is useful. However, regarding biotechnology, the usefulness of the invention might still not be evident. “For example, the creation of a new microorganism or cell line may not necessarily teach the utility thereof.” The United States Supreme Court in the Brenner v. Manson case expressed this view. “It was Howard Ringold and George Rosenkranz, who applied for a patent on an allegedly novel process for making certain known steroids.” They failed to show the utility.[27] Hence, a biotechnology invention has to be sophisticated enough as to reveal a certain benefit that has to be proven in order for it to be patentable.[28]

The courts in the US have made use of a stricter test to measure the usefulness in Biotechnology. It is required that the biotechnology inventions should have a “practical utility”. The US Patent and Trademark Office (USPTO) apply this test to biotechnological and biomedical inventions and if they do not disclose a therapeutic value the inventor is not awarded with a patent. It is sufficient that the invention has one proven area of utility.[29] The requirement of “therapeutic utility” is a difficult threshold, when seeking patent protection for a biotechnology invention. The problem is not that the

[24] *Biotech patents: Equivalency and Exclusions under European and US Patent law.* p. 33.
[25] *Patenting Biotechnology: Inherent Limits.*
[26] http://www.european-patent-office.org/tws/sr-3-b3.htm, 30/12/03
[27] 383 U.S. Supreme Court 519 (1966).
[28] *Patenting Biotechnology: Inherent Limits.*
[29] Ibid.

applicant does not understand the kind of therapeutic utility that can be attributed to the invention; the issue is rather the level of proof of utility demanded by the USPTO. The level of proof demanded is often too expensive in money, or in time needed to produce the necessary evidence. The approach of high demands for display of therapeutic utility is particularly clear when it comes to patent applications on compositions that are claimed to be effective as vaccines; as antiviral, antitumor agents etc. It is not fully clear why this is a reality, since there are therapeutic methods of treatment at hospitals that fail to work as intended every day in hospitals all over the world. The trend is however consistent and this has especially been obvious in cases where the therapeutic utility, that is to say the function as method to cure a medical condition, is the only claimed function of utility.[30]

The difficulty in proving therapeutic utility and the high level of proof demanded has forced the applicants to take alternative routes. A solution, which sometimes has proven to be effective, is to disclose a more obvious and "safe" utility in addition to the intended area of use. To provide an example: a DNA molecule might also be seen as a reagent to prime DNA synthesis in a controlled fashion when producing particularly binding DNA from mixtures.[31]

The Supreme Court in the United States "has stated that discoveries whose only value is as an object of scientific inquiry do not satisfy the utility standard, suggesting that utility could be an important limitation on the use of the patent system to protect research tools."[32] However, if the invention has an element of usefulness to the research society as a laboratory reagent, this will be enough in order for it to be deemed to fulfil the utility requirement. Ultimately this invention that may be a chemical compound can also be useful to the general public if used as a component in another invention. Naturally an invention useful to the general public is also considered to realise the utility standard.[33]

To conclude, in the US the meaning of utility is that a patented invention has to have practical utility. The corresponding criterion in Europe is called "industrial applicability" and for an invention to fulfil this standard it is simply necessary that it is possible to reproduce it industrially.[34]

#### 2.2.1.1 Harmonisation and utility

Concerning the lines to be drawn when it comes to patenting DNA fragments, the boundaries have been discussed under a trilateral cooperation

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[30] http://www.piercelaw.edu/risk/vol5/spring/murashig.htm, 26/3/03.
[31] Ibid.
[32] *Intellectual Property Rights and Research tools in Molecular biology: Summary of a workshop held at the National Academy of Sciences 1996 February 15-16 (Published in 1997)*, chapter 2: Patenting Research Tools and the Law, http://books.nap.edu/books/0309057485/htmlindex.htm, 28/10/03.
[33] Ibid.
[34] *Biotech patents: Equivalency and Exclusions under European and US Patent law*, p. 44.

project. It is the United States Patent and Trademark Office (USPTO), the Japan Patent Office (JPO) and the European Patent Office working together to compare their interpretation of the patent criteria and also to attempt to harmonise it to provide a more efficient treatment of patent application.[35] A comparative study between the three patent offices was made a few years ago as a response to an evolving biotechnology industry, including fields of research where DNA fragments are frequently used. Another important reason for this study was the interesting questions on patentability, that arise in relation to DNA fragments and that this discussion creates a lot of public attention.[36]

It was concluded by the trilateral parties that the practice in all three countries indicates that a mere DNA fragment without utility or function cannot be patented as an invention. On the other hand, a DNA fragment, which discloses a special utility as a means for diagnosing a specific disease, is patentable, as long as there are no other reasons for rejection of the patent application.

#### 2.2.1.2 The revised USPTO Guidelines

The USPTO decided in 1998 that it was possible to be granted a patent for a gene fragments, such as expressed sequence tags (ESTs), provided that the patent application disclosed "a genuine function". In 2001 USPTO saw it necessary to be more restrictive in its practice and issued revised guidelines on the examination of patent applications. The new guidelines clarified that patent applications must disclose "a specific, substantial and credible utility".[37]

### 2.2.2 Experimental use exemption

A patent may be complicating matters for a pharmaceutical company in their manufacturing of a drug or the conducting of clinical trials. It may be necessary for them to obtain and pay for a license. There are however an exemption to the rule that it is necessary to ask permission from the inventor or the owner of the patent. It has been known as "experimental use exemption" or "research exemption from infringement liability".[38]

This exception is somewhat debated and has arisen in the judicial opinion where it has to some extent proven effective in court decisions. It has been enacted in the British legislation in Section 60 (5)(b). This rule guarantees immunity from infringement liability for acts relating to the subject matter of the invention if these acts are of pure experimental character, without a

[35] More on the trilateral cooperation between JPO, USPTO and EPO under headline 2.4.
[36] Trilateral Project B3B, Comparative study on biotechnology patent practices, Theme: Patentability of DNA fragments, http://www.european-patent-office.org/tws/sr-3-b3b.htm, 30/12/03.
[37] http://www.oecd.org/dataoecd/42/21/2491084.pdf, 5/1/04.
[38] Ibid.

commercial result.[39] In the US the courts have recognised on several occasions that there is such a rule existing in theory and it has been argued several times before the courts as a reason for use of a patented subject matter as a part of research. However, the court has been consistent in denying this as an argument for being admitted immunity from infringing a patent.[40]

I will try and determine shortly what "experimental use" is. It is difficult to determine the boundaries, since a lawsuit claiming infringement of a patent is generally not filed in cases where the subject matter of the patents is used only in a closed laboratory somewhere at a university and where the result of the exploitation is not one of any commercial interest.

An infringement of the patent owners exclusive rights consists for example, in the mere employing or using of a patented subject matter, whether it is a product or a process, if it is without the consent of the owner. More precisely the owner of the patent is endowed with the right to prevent someone from conducting in that kind of behaviour, which is illustrated in article 28 of the TRIPS Agreement.

The cases in, which it is of interest to the owner of the patent to file a lawsuit on patent infringement, are mostly the cases where there is some money at stake. As a rule, it is the plaintiff that wins the battle in those cases. Experimental use is hard to claim and there is little space in the American case law, which indicates that this should be a measure to claim to speed up the progress of research and development.[41] I will present an example that is rather revealing:

It is the case *Roche v. Bolar Pharmaceutical Company* from 1984[42], which was a decision from the US Court of Appeals for the Federal Circuit, the court rejected the arguments put forward by a generic drug maker that the clinical trial of a patented drug for the purpose of producing later its own version when the patent had expired, was to be considered as experimental use. The court further explained that it was not allowed to conduct experiments if the intention was to apply the results to ones own business. This was the case, as the manufacturer of the generic drugs, had not received permission in the form of a license to conduct these trials. The situation would have been different if a patented subject matter had been experimented without of pure curiosity or for "strictly philosophical inquiry".[43]

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[39] Lionel Bently and Brad Sherman, *Intellectual Property law*, 2001 Oxford, Oxford University Press, p. 506.
[40] *Intellectual Property Rights and Research tools in Molecular biology: Summary of a workshop held at the National Academy of Sciences 1996 Feb 15-16 (published 1997),* http://books.nap.edu/books/030957485/html/index.html, 28/10/03.
[41] Ibid.
[42] 733 F. 2d 858 (Fed cir.), cert denied, 469 US 856 (1984).
[43] http://books.nap.edu/books/0309057485/html/index.html, 28/10/03.

The view regarding what is to be considered "experimental use" may differ from country to country depending on the interpretation of the term by the courts. It is thus thought that this particular doctrine may have important effects alongside the patents within the field of biotechnology. This is primarily the case, since patenting now is becoming a part of the university sphere in other parts of the world than the United States.[44]

### 2.2.3 Patents on living material- examples

The US Patents Office issued the first patent on an animal on the 12th of April in 1988. The patented animal was a mouse, whose permanent gene line had been engineered with human and chicken genes to give it cancer. DuPont owns the patent on the "onco mouse" and the research leading to the patent was conducted at Harvard University. The patent granted for "onco mouse" is extremely broad and possibly one of the broadest ever granted. DuPont is entitled to intellectual property protection for any animal species what so ever, whose gene lines are engineered so as to contain genes causing cancer. The patented mouse is well known worldwide and it is also trademarked as the Onco Mouse.[45]

Another example concerns a sheep named Tracy, which is considered as a "biotechnological invention" and a creation of the Pharmaceutical Proteins Ltd. (PPL). Tracy is labelled a "mammalian cell bioreactor", since her mammary glands have been genetically engineered through the insertion of human genes to produce a protein for the pharmaceutical industry. When asked, the director of PPL confirmed that the production in the "protein factory" ran smoothly. To be able to continue production however it became necessary to clone Tracy. The result was the famous sheep Dolly, which was endowed with the same set of genes as Tracy, enabling her to continue the valuable production of protein. She was "created" by scientists of the PPL and Roslin Institute and was subsequently patented as an invention of Roslin and the property of PPL.[46]

There are several other controversial examples that also could be considered. US firm Biocyte holds a patent on all umbilical cord cells from foetuses and newborn babies. Another important example is two patented breast cancer genes. US company, Myriad Pharmaceuticals is the owner of the patents and also has a monopoly on all diagnostic use of the patented gene.[47]

Finally a method for gene therapy was developed by researchers at the National Institute of health (NIH) in the US. The method was evolved in the

[44] *Intellectual Property Law*, p. 506.
[45] *Protect or Plunder? Understanding Intellectual Property Rights*, p. 2.
[46] Ibid.
[47] Ibid.

public domain, but through a long line of proprietors it ended up in the hands of one of the worlds "gene giants", Novartis.[48]

## 2.3 Legislation affecting the exchange of research

The Bayh-Dole Act[49] and the Stevenson-Wydler Technology Act were passed by the US congress in 1980. The intention of the enactment was to permit contractors, small businesses, and non-profit organizations to receive the right to apply for patent on research funded by the government and at the same time create a possibility for the funded unit to transfer the technology to a third party. The legislation has created a climate that is positive for small, research-intensive biotechnology companies, which are closely linked to research universities. University professors founded most of these small firms and many universities now offer the possibility for small companies to be started under their roof provided that collaboration between them is at hand.[50]

The stated intent of the Bayh Dole Act, was to certify that all the patented achievements of federally-funded research was available, in as great extent as possible and to as many institutions as possible, for all types of scientific analysis. The most important consequence of the enactment of the mentioned legislation, however, was a shifted federal policy. Before the enactment it had been customary to put all the scientific results, which had been federally funded sponsored research programs into the public domain enabling access for all. Now, following the enactment, institutions mainly sponsored by the government applied for patents to protect their accomplishments. The federal policy expressed in the two acts was very "pro-patent". It was believed that exclusive rights were necessary to stimulate the research climate and industry, to work as an incentive on the will to invest in new research projects. The theory was that the private entities would be better at commercialising and placing new inventions in the market, than federal agencies. A much welcome consequence would also be that a large part of the financial burden of research and development would be placed on private entities. The Bayh-Dole Act represents a more uniform course of action concerning federally sponsored research and development than had earlier existed.[51]

Now, looking back 23 years later it is possible to determine that the Bayh-Dole Act and its amendments have contributed to a large increase in technology transfer from universities to industries. The technology transfer

[48] Ibid.
[49] P.L 96-517
[50] http://books.nap.edu/books/0309057485/html/index.html, chapter 1, 28/10/03.
[51] Ibid.

is ultimately for public good. The licensing of new technologies has also led to substantial advances in medicine and engineering etc.[52]

## 2.4 Obligations under international law

It is up to the national patent offices to interpret the extension of the patent criteria in accordance with their patent laws. The patent laws have to be in tune with international obligations under different conventions, such as the Paris Convention, TRIPS Agreement and the RIO Convention on Biological Diversity. Declarations adapted by the UNESCO and other international organisations, such as the OECD should also be respected. International conventions have to be implemented in the national legislation. The result may still be different, depending on how the patent offices or the courts choose to interpret the rules incorporated.[53] The procedures for application, the administrative rules and how the patent rules are put down and in what type of legal instrument, may also differ between different countries or regions. Even such an important issue, as who is to be awarded a patent, may be answered differently depending on where you are, in Europe or the United States. In the United States it is the person, who demonstrably is the first to invent, whilst in Europe it is the person, who is first to file, who is awarded the patent.[54] There is international cooperation between the different regions and states, which is intended to make the patent system more smooth and efficient. It has become necessary with all the communication going on between countries in different parts of the world. An example, worth mentioning, is the trilateral programme between the United States Patent and Trademark Office (USPTO), The European Patent Office (EPO) and the Japan Patent Office (JPO). This programme makes the international patenting framework more efficient and transparent. It also does seem logical that in the comparison of the compatibility between their rules they will manage to identify how the systems can be harmonised.[55]

### 2.4.1 The Paris Convention

Then, there is The Paris Convention, the mother of all international industrial property conventions, signed in 1883 by 11 states. It has been revised a number of times and the last was in Stockholm in 1979. The number of members has increased considerably and as of July 15 in 2001 the Paris Convention Comprised of 162 member states. It is mandatory to apply the substantive provisions of the Paris Convention for all the countries, which are parties to the World Trade Organisation (WTO) and

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[52] http://www.ucop.edu/ott/bayh.html, 7/1/04.
[53] Mogens Koktvegaard, Marianne Levin, *Lärobok i Immaterialrätt, sixth ed.*, Gothenburg 2002, Norstedts Juridik, pp. 181-183.
[54] Lionel Bently and Brad Sherman, *Intellectual Property Law*, p. 346.
[55] Fredrick Abbott, Thomas Cottler and Francis Gurry, *The International Intellectual Property System: Commentary and Materials*, Kluwer International Law, 1999 The Hague, p. 838.

bound by the provisions of the agreement on Trade-Related Aspects of intellectual Property Rights (TRIPs Agreement). In its article 2, the TRIPS Agreement obliges Members to comply with Article 1 to 12 and article 19 of the Paris Convention.[56] In the first and obliging provisions, the Paris Convention sets out the objects that are protected by the convention. They conclude patents, utility models, Industrial Designs and Marks. Article 2 also mentions the principle of "National Treatment" for nationals of countries of the union.

### 2.4.2 Trade Related Intellectual Property Rights (TRIPs Agreement)

The TRIPs Agreement, which was signed in Marrakech in 1994 and stands for Trade Related Intellectual Property Rights, is linked to the WTO. It was the WTO, which enacted this agreement. TRIPs, forms part of the Final Act and constitutes the results of the Uruguay Round of Multilateral Trade Negotiations completed within the framework of the General Agreement on Tariffs and Trade (GATT).[57] Voices raised claim that the TRIPs was forced upon by Multinational corporations using the United States Government as a power tool to create more favourable trade conditions. The consequence of the agreement being that its negative or factual impact has been much more notable on the third world countries than the western world. One of the more significant impacts brought by the TRIPs is the limit set on compulsory licenses. An extended patent criterion is also something that has had a negative effect upon the third world countries.[58]

### 2.4.3 The European Patent Convention

The European Patent Office (EPO) under the European Patent Convention (EPC) is an example of regional cooperation. The EPC was originally based on an EC-initiative from 1973 and came into force in 1977. The EPC is no longer exclusive to the members of the European Union it also includes countries like Monaco, Switzerland and Liechtenstein. The original intent was to provide a more centralized and less expensive system for patent application. The EPC concerns patents on the application stage and the EPO takes care of the administration of the convention. The patent applies in one or several of the countries, which are parties to the convention, depending upon request and according to articles 2(2) and 3. Countries, which are members of the European Union, are also obligated to abide by the decisions taken by the EC-court.[59] Their obligations concerning the patent

[56] *Collection of Documents on Intellectual Property*, compiled by WIPO, Worldwide Academy in 2001, p. 20.
[57] Ibid, p. 20.
[58] Ibid. and *Protect or plunder? Understanding Intellectual Property Rights*, pp 95-97.
[59] *Lärobok i Immaterialrätt*, pp. 44.

criteria as applied to biotechnology, also include the biotechnology directive.[60]

### 2.4.4 The Patent Cooperation Treaty

The Patent Cooperation Treaty (PCT) came into force in 1978. The intention was to provide a system with the possibility of an international application and preliminary examination procedure. The PCT has the responsibility of doing preliminary research and taking administrative precautions and in the end it is up to the local and national patent offices to decide whether a patent application is accepted or not. This system has as one of its positive effects, the reduction of fees.[61]

### 2.4.5 The Rio Convention on Biological Diversity

The Rio Convention on Biological Diversity was signed in 1992. There are 179 signatories to the convention and although it is not directly concerned with the patent standards, it still signifies a change in attitude towards how natural resources should be exploited and treated. This may ultimately have an impact on how the natural resources are treated and it may contribute to challenge the pro-patent view that has been in reign for the last 40 years or so.[62]

### 2.4.6 A universal solution

The wish for a single coherent universal patent system, with only a single patent application to be protected all over the world, has been formulated. Currently it is not possible to apply for and obtain international patent protection. Therefore, when a company is claimed to have patent protection for a pharmaceutical product world wide, the truth is that they have had to apply for patents in all the different countries and regions of interest to them.[63] When considering this time consuming method for obtaining patent protection for a medical drug intended for an international market it is easy to see the interest to harmonise the interpretation of the legislation between Europe, Japan and the US to obtain a more efficient and less costly process of receiving patent protection in a large part of the world. At the present time the international cooperation is as above mentioned.

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[60] 98/44/EC.
[61] *Collection of Documents on Intellectual Property*, pp. 55-56.
[62] *Intellectual Property Law*, p. 322.
[63] http://www.msf.org/content/page.cfm?articleid=ADA6508E-8907-4010-98650D3E93, 8/12/03.

# 3 Why do we need a patent system?

"A patent gives the patent holder the exclusive right to his invention covering the making, exercising, selling or distribution of the patented article or substance, as well as using and exercising the patented method or process of manufacturing an article or a substance."[64] Patents mainly serve an economic function and preserve the economic rights of the inventor or the owner of the patent. The central policy when adopting a system for patent protection should be the attributable incentive to innovate through the economic power belonging to an exclusive right. Li Westerlund recognises this idea in her thesis "Biotech patents: Equivalency and exclusions under European and US Patent law", where she refers to a statement by Giles S. Rich.[65] The governing conviction is that the private protection, which is limited in duration, shall promote the will to develop and invest in new ideas and products. The innovation process is ultimately stimulated to create benefits to society. In the judgment taken by the United States Court of Appeals in Amgen v. Genetics Institute, Inc, the crucial importance of being able to patent drugs for the sake of promoting and supporting development of pharmaceuticals, was emphasised. The following statement was made in the judgement: "For novel therapies and diagnostics based on specific DNA sequences, the possibility of having patents granted for achievements in the field of biotechnology has promoted industrial competitiveness and continues to do so." This particular case treated the relevance of including DNA sequence information in an application for patent protection regarding Erghropoietin. This drug is said to be one of the drugs, which has generated the highest profit in the world (1.5 billion dollars a year).[66]

The patent system should, according to Westerlund, be seen as a contract given to the inventor, that he or she holds to give something new and innovative back to the public, while at the same time being awarded with the right to control the exploitation of the invention for a limited period of time. It is the question of private and civil rights, which when the system has the effect intended, work in harmony with the broader acclaimed rights of the people in society. The right to claim and seek intellectual property protection is also considered by many to constitute a human right.[67] Article 27 of the Universal Declaration of Human rights concludes two rights that sometimes collide. In the first paragraph the interests of the general public to take part in cultural life and enjoy scientific advancements is illustrated, while the rights belonging to the inventor or author are described in the second paragraph. These rights are as mentioned intended to flourish side by

[64] *Protect or Plunder? Understanding Intellectual Property Rights*, p. 6.
[65] *Biotech Patents: Equivalency and exclusions under European and US Patent Law*, p. 9 and footnote 62.
[66] Ibid.
[67] Ibid.

side, but the reality is sometimes different. The question is if this right to intellectual property protection can be damaging to R&D, or if in the end it will prove to be the best solution for stimulating the research environments within biotechnology and the life sciences. Westerlund points out that the actual positive effects that a patent system has on the technological and scientific progress in general, is difficult to estimate and sometimes ambiguous. The results are different depending on what type of industry is kept in mind.[68]

When considering the effects the patent system has upon the industries, which are engaged in human-health related research, it is obvious that they are typically representing a market where the stakes are high and where large sums of investment as well as long-term investment relationship are normal. The biotechnology industry has also classically been looked upon as a field where the patent system really works as an incentive upon the will to invest and innovate. It is important though, to maintain a balance so that the patent system awards enough financial remuneration to stimulate scientific advancement while not impeding competition in a too large extent.[69]

Although, being granted a patent for an invention signify that you as a patent holder enjoy exclusivity in the exploitation of that invention, it will still mean that this protection is only valid in the country, where it was awarded. This means that internationally this does not prevent research without the permission of the patent holder in the US from being conducted in the same area. It only means that the owner of a patent can prevent import of goods due to unauthorized use of that patent.[70] It is also important to keep in mind that there is a time limit for the patent protection of 20 years in Europe, Japan as well as the United States.[71] After this period of time has elapsed the protected product or process falls in the hands of the public. Since, science is advancing rapidly within the fields of biomedicine and biotechnology this period of time can seem long. However, the intention with the patent as an institute is not merely to provide protection to the inventor to prevent others from exploiting the invention, it also functions to keep the knowledge of the invention available to the public. This is carried out through the part of the patent procedure that is called disclosure. A disclosure is made through a patent application filed with a patent office, which is required[72] "to contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise

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[68] Ibid.
[69] Ibid. pp. 9-10.
[70] *Who Owns That Gene? AgBiotech and Intellectual Property*, AgBiotech Buzz: Intellectual Property, Volume 3 Issue 1, March 3, 2003, http://pewagbiotech.org/buzz/print.php3?StoryID=91, 24/11/03.
[71] Article 63 of the European patent Convention, art 33 of the TRIPs agreements http://www.oecd.org/dataoecd/42/21/2491084.pdf, 5/1/04, p.26, www.usptogov/web/offices/pac/doc/generalindex.html#patterm, 10/12/03.
[72] http://www.piercelaw.edu/risk/vol5/spring/murashig.htm, 26/3/03.

and exact terms as to enable any person skilled in the art to which it pertains, or which it is most clearly connected to, make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."[73] There are three main functions to be satisfied through the element of disclosure. The first is to identify the invention for the intention of notifying society of the patent content. The second is to provide a basis for the scope of the patent. Finally, the third function is aimed to explain how the patent should be applied and used.[74]

The positive effects of a well-developed intellectual property protection system with a realistic approach to science and progress may still be the best solution in favouring R&D. There is a good reason why the patent and the protection and recognition that is linked to this institute, have a positive effect on creating and scientific progress.

The question if the intellectual property protection system manages to achieve the goal to function as an incentive to invest and innovate, is not a question, which can be answered with a simple yes or no. It is fairer to direct the question to a professional group within a particular field of science or industry. It is rather unlikely that people will stop inventing and introducing new products or processes, simply due to the lack of an effective system for patent protection. Companies, which are earning direct profit from introducing new technologies to the market, would probably survive nonetheless. It may be motivating enough to be the first firm on the market with that particular product. Certainly, there are some fields where the patent really fulfils the intended functions as an incentive, stimulating the will to invest and to make the result of research more public.[75] It is also important to keep in mind that the system for intellectual property protection is an institute that has grown over the centuries and, which has been established and adapted to satisfy a need. The need is to claim intangible property as property and for the proprietor to be named as the inventor.

[73] 35 U.S.C Sec 112, [[paragraph]] 1.
[74] *Biotech patents: Equivalency and Exclusions under European and US Patent law*, pp. 59-60.
[75] http://boks.nap.edu/books/0309057485/html/index..html, 28/10/03.
[76] *Biotech patents: Equivalency and Exclusions under European and US Patent law*, p. 25.

# 4 Bio-health related research

## 4.1 DNA and genetics

A gene is built up from an ordered sequence of nucleotides, deoxyribonucleic acid (DNA) to be found in a particular position on a particular chromosome. It is the very condition for all types of man-made changes in any material, which are able to reproduce themselves or that, can be reproduced in a biological system. DNA on the other hand is a molecule in the chromosome and is also the depot of genetic information in all organisms. This resulting in that the determination of the structure and different functions is based on its coded information. DNA is directly or indirectly involved in the production as well as the reproduction of the cell, whether an animal, a plant, a human or an organ.[76] The human genome in its turn is all the genetic material contained in a cell or a human being.[77]

## 4.2 Biotechnology

Biotechnology has evolved rapidly during the last two decades as a mean for causing genetic recombination through the use of molecular means instead of sexual. Foreign genes can be inserted into cells allowing them to make proteins they have never been able to make before.[78] It has also been explained as "The branch of molecular biology that studies the use of micro organisms to perform specific industrial processes".[79] It is the question of applying science and engineering through the direct or indirect use of living organisms, whether it is in their natural or a genetically modified form. It is the solution to very small-scaled problems with large quantity results. To better understand its results I will clarify with a few examples.

Biotechnology is the tool to achieve results in, for instance, stem cell research. Stem cells are cells with the potential to grow into 300 of the different kinds of cells in the human body. They are also endowed with the

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[77] *De A comme acide à P comme protéine*, Le Monde, 9/4/03, http://www.lemonde.fr/article/0,5987,3244--316058-,00.html, 15/04/2003.
[78] *Biotech patents: Equivalency and Exclusions under European and US Patent law*, p. 7.

[79] http://www.thefreedictionary.com/biotechnology, 8/12/03.
[80] http://www.i-bio.gov.uk/UkBioportal/Beginners/html/stem.html, 8/12/03.
[81] http://www.lemonde.fr/article/0,5987,3244--316058-,00.html, 15/04/03.
[82] *Biotech patents: Equivalency and exclusions under the European and US Patent Law*, p. 16 and http://www.i-bio.gov.uk/UkBioportal/Beginners/html/cloning, 8/12/03.
[83] Etiology is the study of what causes disease, whether it is hereditary predispositions or external factors such as bacteria and viruses. www.ne.se/jsp/search/article.jsp?I_art_id=16492&I_word=etiology, 2/12/03.
[84] http://www.thefreedictionary.com/molecularbiology, 8/12/03.

ability to divide for indefinite periods of time before they take on the form of a specialised cell. Due, to these qualities they are very useful when it comes to research involving understanding of the cellular changes in the development of human beings and also for the cultivating of cells turning into tissues, which can replace damaged tissues.[80] Another area, which is included under the biotechnology umbrella, is the use of genetic engineering as it is applied, in for example the method of "cloning". Genetic engineering consists in the manipulation of genes and in the case of cloning this means to transfer genetic material from one organism to another. A famous example is of course the sheep Dolly. Genetic engineering is a more efficient way to obtain the same results as that of classical breeding. The art of genetic engineering has also been used to give animals human genetic conditions, such as cancer. Normally, the animals are not afflicted with those diseases, but through the genetic engineering of human "susceptibilities" into the genome[81] of the animal, this is possible.[82]

Biotechnology is a tool used in the research for creating new drugs and as an alternative to more traditional pharmaceutical methods. The more traditional ways consist basically in going out in nature and collect samples of different organic compounds, analyse them and carry out different trials to determine if the samples are interesting to medicine or not. Obviously this is a rather ineffective way of drug discovery. Through the use of biotechnology, it is possible to carry out more targeted experiments and therefore it is a tool in the search for new drugs that saves time and money. Biotechnology is concluding the advances within molecular biology and genetic engineering. It is through focusing on the etiology[83] of the disease at a cellular and genetic level that the process of drug discovery is made more rapid, efficient and thereby, less costly.

## 4.3 Molecular biology

So how does Biotechnology fit together with molecular biology or biomedicine? Molecular biology is a "branch of biology that studies the structure and activity of the macromolecules essential to life and especially with their genetic role.[84]

## 4.4 Biomedicine

Biomedicine on the other hand is the part of medical science that uses biological and physiological principles in the exercise of clinical practice. The principles come from the natural sciences and they are applied to medicine.[85]

[85] http://www.thefreedictionary.com/biomedicalscience, 8/12/03.

## 4.5 The Human Genome Research Project

Another issue to be mentioned under these circumstances is "The Human Genome Project" (HUGO-project), which was terminated in 2003. This project was initiated in the early 1990s and consisted in the mapping and decoding of the human genome. It was a project joining together several different nations, such as France, China, Germany, the US, Japan and the UK. The mission of the research group was detecting and sequencing of the 3 billion letters representing the DNA code, to be able to find the cure for many severe diseases. It was also intended to provide the basis for better understanding of the hereditary factors leading to diabetes, heart diseases and different mental disorders. A third goal was to in a relatively near future be able to sequence and decipher the genome of a patient for a cost less than 1000 US Dollars or 930 Euro in the monetary value at that time.[86] With the knowledge achieved under the process of the HUGO-project it is now possible to identify persons at risk of being afflicted with certain conditions and the development of therapeutics is hence based on this information. Personalized medicine is also feasible and the knowledge of the genetic profile of an individual is used to determine the drugs or therapeutics, which are suitable for that particular person. Diagnostic tests are also potential to clarify how the person will respond to a specific drug and if it will be effective. This provides a more safe and efficient means for trying drugs in the long run.[87]

[86] http://www.lemonde.fr/article/0,5987,3244--316866-,html, 15/04/03.
[87] Ibid. and http://www.i-bio.gov.uk/UkBioportal/Beginners/html/medecine.html, 8/12/03.
[88] Robert & Barbara Luciano Professor of Law at the University of Michigan Law School and the participant of a conference sponsored by the Engelbert Center on Innovation Law and Policy and the New York University School of Law, which was held in Florence.

# 5 The structure of research exchange

## 5.1 General remarks

I will under this headline present a changed structure in the exchange of information relative to biotechnology and biomedicine, which according to theory has lead to disturbances in research and development. The theories of a change in the infrastructure and the problems that can be caused, is amongst other things due to the emerging of new institutions and that established institutions, such as research universities are presented with new roles in the exchange of research information. In the words of Rebecca S. Eisenberg[88]: "Current problems in the exchange of biomedical research tools arise in the context of dramatic institutional and cultural changes in biomedical research that have not yet come to rest."[89]

As earlier mentioned, the variety of different actors in the field of biotechnology has increased. There are now new types of institutions seeking intellectual property protection for their scientific advancement, while attempting to make additional profit. An example is the appearance of commercial biotechnology firms in market niches belonging somewhere in the middle of the research chain. They are conducting research and developing products which are neither to be considered as belonging to initial and fundamental research nor are they end products[90] resulting from cumulative research. These biotechnology firms are different from the big pharmaceutical corporations on fundamental points. They are often founded by scientists coming from an academic environment and who also in their work, choose to uphold a strong liaison, financially as well as scientifically with the academic world. The biotech firms are being awarded some government financial support and they finance their activity by selling research tools.[91] The small biotech firms are also relying very much upon the knowledge and capabilities of their scientific personnel. It is therefore of great importance that the products and achievements of those companies are protected as industrial property. It is a way for those relatively small biotech firms to form an important part in the cumulative research chain, so that other actors further down the line are dependent on their work to conduct their own research resulting in an eventual end product.[92]

[89] *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society*, p. 226.
[90] The term end product is explained under headline 5.1.1 and 5.3.
[91] The term research tool is explained under headline 5.1.1 and 5.3.
[92] *Expanding the Boundaries of Intellectual Property: Innovation for the Knowledge Society*, p.227.

Another issue with significance to the exchange of research tools is the economic structure and balance, which have transformed, due to changes in research policy and the emerging of new actors in the biotechnology research arena. The biotech research funding is heading towards a balance between the private and the public sectors, where the private sector is the biggest contributor and the public sector, despite increased governmental support to health-related research, is left behind. The university-based biomedical research is mainly sponsored by public funds. The boundaries are nowadays rather hazy with regards to the relations between the academic institutions and the private firms committed to research in the life sciences. Collaborative research between different types of institutions, where the research and funds are placed in so-called patent pools, is quite common, especially among the different institutions in the public sector. Different institutions are sometimes competing in the same fields and sometimes working together to reach their respective goals. This situation creates difficulty in determining whether the universities are in fact commercial rivals.[93]

In this competitive surrounding, it is understandable that the institution responsible for the development of a product, new material, process or piece of information, also considers it of vital importance that these tools are awarded patents. A patent makes it possible for an institution to make profit by licensing the achievements or selling them to others.[94]

### 5.1.1 Research tools

The term “research tool” is used to define whether, for example a pharmaceutical company is a mere component in their research, while to a small biotech firm it constitutes the finalized work. However, the chosen name designates a product, process or method, which is useful or necessary to achieve another goal. The fact that the research tools to some is the goal and to others a component, creates a situation where they are valued differently depending on the institution and how much they are relying on them.[95]

The conditions for gaining access to a research tool of high value can be provocative in relation to research institutes, pharmaceutical companies or others in need of the research tools as a part of their research. I use the term provocative, since a pharmaceutical company in need of a certain product as a part of the manufacturing of medical drug, will not appreciate the value of this product, since it, to that company is a mere ingredient. It is a product of importance as a necessary component in the pharmaceutical product, but it is not something of commercial value to the general public, such as the case is with a pharmaceutical product. However, there are other problems that

[93] Ibid. pp. 227-228.
[94] Ibid. p. 228.
[95] Ibid. p. 231.

might delay research more. The endless negotiation around the terms of the agreements for everyday use of information, methods or data has become a serious issue to be taken into account. The administrative procedures around this type of product, method or information are a real obstacle to scientific advancement.[96]

### 5.1.2 Main issues

Rebecca Eisenberg sees four main issues creating problems in the establishment of a functioning market for the exchange of research tools after having conducted interviews with several participants in the biomedical market. The first of these issues is the phenomenon of transaction costs. It would appear, according to what Eisenberg has experienced, from talking to biomedical scientists, like the real problem lies within the domain of the low value exchange of research tools. Transaction costs are thus more probable to disturb the transfer of research tools, which are used in experiments somewhere in the middle of the cumulative research chain and without real commercial value.[97]

A second problem in the machinery for transferring biomedical research tools is the differences occurring between the many institutions taking part in the exchange. Research universities, biotech firms or pharmaceutical companies are often of different opinions about their roles in the research community. They are also inclined to think that they are entitled to the results of the other party and at the same time they are very fast to apply for a patent so as to keep the achievements within their own entity. The enactment of the Bayh-Dole Act has created an environment where the representatives of university research are being accused by the actors from the private market, like pharmaceutical companies, of being too interested in profiting from their work by protecting it as Intellectual Property. At the same time the research universities are claiming that since they are conducting research to serve the general public they should be entitled access to certain results from research being conducted by other institutions. In short, representatives from different corners of the field of biomedicine are having troubles in reaching licensing agreements.[98]

A third problem can arise even within the same institution. Internal conflicts regarding company policy on the use and exchange of research tools are also rather common. Differences are frequent between the scientists using the research tools in their every-day work and the lawyer and business people hired by the management of the company to negotiate agreements in relation to other companies or universities conducting research.[99]

[96] Ibid.
[97] Ibid. p. 231.
[98] Ibid. pp. 231 and 235.
[99] Ibid. pp. 231-232.

The fourth major problem concerns the evaluation of biomedical research tools and as a consequence the importance of the contribution possible by the particular object to future research. Much speculation is involved in this type of evaluation, since it is often a question of new research results being outsourced, which are not really comparable to other research tools on the market.[100]

## 5.2 Transaction costs associated with license agreements

According to article 28(2) of the TRIPS Agreement the holders of a patent "…have the right to assign, or transfer by succession, the patent and to conclude licensing contracts. The holder of a patent may very well be interested in seeing that the patented biotechnology invention is applied in research and that it can contribute to the development of a pharmaceutical product or a method to carry out diagnostic testing. This can be achieved by concluding of license agreements. The user of a patented material has to pay an amount, or maybe another type of revenue is agreed upon and in return access to important research material and information is gained. These license deals provide the possibility for research to continue and develop.[101] There is however certain issues connected with transactions being made. I will develop these issues or problems here below.

First of all, even though the licensing contracts provide opportunity to access important material, the cost might still be too high, especially when not knowing with certainty the result of a scientific application of the patented material. This is often the case with genetic material.[102] Licensing agreements concerned with an invention of high value are due to the mentioned character, naturally prioritised above the deals remarked by larger frequency and lower value. For high-value transactions there are more sophisticated solutions being developed, such as for example "patent pools"[103]. So, it is normally the deals, which are more routine in their character or at least of a lesser importance, which cause problems and lead to an exchange of information that is not very efficient.[104]

More long-term collaborative research is frequent in situations where the transaction of a research tool is of high value. A high valued instrument is a piece of information, a process or a product, which is believed to contribute

[100] Ibid. p. 232.
[101] http://www.oecd.org/dataoecd/42/21/2491084.pdf, 5/1/04, pp. 12-14.
[102] Ibid. p. 14.
[103] Patent pools are suggested is a solution that can be used to prevent patents from piling in top of each other (patent thickets). The idea is that several owners enter their patented inventions into a common pool in order to facilitate the necessary license agreements. This solution promotes the development of new products.
http://www.oecd.org/dataoecd/42/21/2491084.pdf, 5/1/04, p. 66.
[104] Eisenberg, *Bargaining over the transfer of proprietary research tools: Is this market failing or emerging?* p. 232.

to the development of a future product of importance to science in general or maybe to the general public as a medical drug. The lower valued transactions, since they are often overlooked in the chase for achieving more substantial goals, do constitute a delaying factor in the exchange of information and subsequent advancement within the field of biomedicine and biotechnology according to representatives for biotechnology firms and pharmaceutical companies. People responsible for negotiating the terms of agreements in transactions have also confirmed this.[105]

Representatives of universities appear to be experiencing problems with the quantity of transactions of low value taking up their time and at the same time they are disturbed by not enjoying access to the more interesting higher valued research tools. Big pharmaceutical companies also fail in the bargaining for research tools and the impact of this failure is often high enough for it not to be ignored. A representative of an influential pharmaceutical company, who used to be a scientist, concludes that the bargaining for a license on a research tool can take as much time as up to one year. If it takes such a long time it is usual that the scientists give up and try another solution. She also admits that the firms she is representing are not always willing to renegotiate the terms around their research instruments either, since they might not be interested in putting the effort that this would demand. If the requesting party does not agree with the standardised form of agreement around a certain tool the providing party has no alternative but to offer the patented research tool to another interested research institution. A representative of another pharmaceutical company stated: “the deal breaker (in negotiations over the transfer of research tools) typically isn’t cost, but terms”.[106]

What more specifically is so difficult to agree upon is where future value and risk are to be placed. What is to be kept in mind is that not all transactions of research tools will generate future value in their applications. Keeping this in mind, a strategy sometimes used has been developed. It consists in carrying out the more substantial part of the negotiation after the situation is clearer regarding the value involved in the transaction. This is a system, which is likely to reduce the transaction costs involved. A more doubtful way in doing this is to use patented research tools without permission and hence without a license and with intention to settle matters later providing that they have discovered something of future interest. If not, they will probably never be caught with this behaviour, which infringes the intellectual property rights of the patent holder.

Another way around the endless negotiating of terms to get access to information is used by other firms and they try to settle matters by deciding to divide future value of intellectual property between them and hence they have to wait for achieved results and then return to negotiate the more specific conditions at a later stage. A lawyer advocates that this solution

[105] Ibid. p. 233
[106] Ibid.

works in certain cases. What he means is a strategy where his company provides their archive of combinatorial chemical compounds to other companies, which compares those to their own "proprietary biological targets". The lawyer was irritated by the inefficiency of long and fruitless negotiating and therefore decided to come up with simpler forms of agreement, which he proposed to the interested firms. The main condition was that they would be coming back to negotiate in the case of a match between the chemical compound and the biological targets in the hands of the interested party. He managed to conclude seven deals of that kind in a year out of the proposed fifteen. The subsequent negotiations of the terms around these matches took time, but the lawyer was still pleased.[107]

Progress is depending on a rather easy flow and exchange rhythm of low valued information and materials. If those lesser-valued research tools at the same time were weighted by intellectual property claims the risk would be a situation of inequality between the actual cost of the transaction and the realistic value of the tool. A complicated scientific structure in biotechnology or biomedicine working like that can possibly hinder important transactions from being made.

## 5.3 The relationship between research tools and end products

By naming an invention or a piece of information a "research tool", it is implied that it is the perspective of the user on this particular piece of information or method that has been taken into account. One single instrument can constitute a research tool to one actor in the field, since it can be used merely to contribute to another result and it might at the same time be another party's end product. This is possible, since there are some biotechnology firms, which are specialised in developing proprietary materials, information and methods that are functional only in further research. Obviously, to these companies the research tools that they supply to others in the business are "end products" and the intended goal with their research or production. There is also the other way around to be considered. There are products, which to a great deal are mere fractions in the research chain and which at the same time may have a potential or factual value to non-research consumers. To further explain; "a pharmaceutical compound might be used in academic research and a DNA sequence that is associated with disease might be marketed as a diagnostic product at the same time that it is used in further to understand its role in a disease pathway."[108]

Another term to be mentioned in the same breath is "cumulative research". It is research that results in several results on the way to a final result in the shape of a marketed product. For example, a medical drug may contain

[107] Ibid. pp. 233-234.
[108] *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society*, p. 228.

many patents, since the idea is, not to patent the drug itself, but rather an invention. As a result one single drug can contain both product and process patents. There are companies doing basic research for the treatment of a particular disease and they may in their work invent a new chemical entity or molecule and to be rewarded for this discovery they apply for patent. They may also be awarded patent for the method of applying the material. Perhaps years later other scientists may come to the conclusion that the very same chemical entity or molecule is applicable in another medical treatment and a new patent is thus filed for a new type of use.[109]

The access and supply of research tools have been widely discussed. There are, for instance, several large and influential pharmaceutical companies, earning their profit by selling proprietary drugs to non-research consumers, which argue for easier access to research tools. This is not very surprising when taking into account the role they play in the market. These pharmaceutical companies are naturally interested in getting there own product out to possible consumers at the lowest effort and cost possible. As a consequence the same company also is very restrictive when it comes to their own medical products developed and are not inclined to share them with researchers from other institutions.[110]

It is difficult to come to a standard solution to facilitate the exchange of research tools. An explanation is that a patented research tool has different importance and value depending on whom you ask, the supplier or the user. The tendency is to put a high value and importance on the own property, while awarding research tools belonging to other institutions with a lesser value. Different types of agreements are used depending on whether a research tool is patented or not. If a research tool is believed to contribute to a product of commercial value, the contract terms are more complicated and less standardised.[111]

### 5.3.1 Issues associated with research tools

The terms of the license agreements, permitting others than the proprietor to use a patented research tool are quite different depending on what is agreed between the contracting parties. In some cases proprietary research tools have been used under license by several pharmaceutical companies, according to conditions that permit the research to advance, while allowing revenue to the owner of that particular research tool. There are two most interesting cases worth mentioning in the spirit of this discussion and which have had an impact on the biomedical research. The “Cohen-Boyer patent” on recombinant DNA technologies owned by Stanford University and the University of California have expired.[112] Another patent that has expired is

[109] http://www.msf.org/content/page.cfm?articleid=ADA6508E-8907-4010-98650D3E93..., 8/12/03.
[110] Ibid. pp. 228-229.
[111] Ibid. p. 229 and http://www.oecd.org/dataoecd/42/21/2491084.pdf, 5/1/04, p. 14.
[112] Ibid. and http://books.nap.edu/books/0309057485/html/index.html, 28/10/03

that relating to the polymerase chain reaction (PCR) and the intellectual property rights used to belong to Hoffman-La Roche.[113] Both of these patents have created new technology solutions and have had impact on several different areas of research and they have also been licensed in a way permitting widespread use and development.[114]

An issue of concern regarding research tools is a lack of efficiency in the exchange of information and products. This is a fact proven by that it is often the same provisions that are being argued over and over. The terms in the proposed agreements are often of standard character and quite tough and this generally leads to the need for new negotiations in order to conclude the deals. There are different explanations for this lack of efficiency. One is that there are lawyers profiting from renegotiating deals and another is that a deal might have been concluded based on an agreement that is also as a matter of convenience used in other deals.[115]

There are other conflicts arising regarding the access and right to profit from the research tools, which are well worth mentioning and probably even more complicated in their nature than what I have mentioned earlier. The existence of "reach-through" and "grant-back" provisions in agreements, which administer the access to future inventions, are being discussed. These clauses may have crucial effects and are therefore debated to a large extent. Providers of an important research tool normally try to profit in the form of royalties on the sale of future products or options to future licenses being issued on a patented product of piece of information. Sometimes a research tool is licensed under condition that the provider retains the ownership of a future developed product. This way the provider of a research tool may have a piece of the cake with far more possible future value than the instrument provided. The provider may also be scared of future intellectual property claims being directed against them and will therefore seek to have licenses on the result that their research tool is part of. The will of everyone involved to profit from and at the same time protect their own research is creating a thicket forest.[116]

[113] Ibid. p. 43-46.
[114] *Expanding the Boundaries in Intellectual Property: Innovation Policy for the Knowledge Society*, pp. 229-230.
[115] Ibid. p. 230 and footnote 26.
[116] Ibid. pp. 230-231.

# 6 Identifying the institutions and their problems

## 6.1 Research universities and dedicated biotechnology firms

The universities conducting research has played a crucial part in laying the important groundwork for biotechnology. This happened to occur together with a fundamental change in the custom of the universities in terms of how they conducted their research. The level of the evolution of science in the fields of biotechnology and biomedicine were demanding cooperation and exchange of academic specialities. This proved somewhat difficult to the research universities, bound as they were by conventions in their manner of conducting research. The young, science-based and dedicated biotech firms (DBFs), which were often founded by academic researchers, did not experience the same problems, since they were not as tied by conventions and traditional ways of practice as the universities. Research Universities have made changes in their biological departments as a response to a biotechnology industry that has evolved rapidly particularly during the 1980's and 1990's. They now participate in the race for patenting genetic inventions.[117]

The exchange of information and products between the academic world and the biotech companies has now become frequent and is creating new roles for them. The biotech companies are also engaged in basic research and giving birth to research tools and sometimes also in collaboration with universities. These firms are often started under the roof of universities. Within the universities a spirit of entrepreneurship has spread to a new character emerged: "the scientist-entrepreneur". A big reason for this is naturally that the biotech companies are doing a good job in basic science. A second reason is that biomedical research is still a popular field of research to support with traditional federal resources and at the same time a spirit of commercial interest is flourishing in the whole research community. The phenomenon of the "star-scientist", even if coming from an academic environment has also spurred the commercialisation and re-structuring of the whole community. Finally, the passing of the Bayh-Dole Act, already mentioned above, has had an impact on the changing of the infrastructure and justifies profiting from academic research.[118]

[117] Powell W.W, *Networks of learning in Biotechnology: Opportunities and Constraints Associated with Relational Contracting in a knowledge Intensive field* in *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* p. 254.
[118] Ibid. pp. 254-255.

## 6.2 Government institutes

In a country such as the United States, the National Institute of Health (NIH) has had a tremendous influence on the funding of medical technologies as well as the conducting of research. NIH distributes research funds both to universities and private research institutions. Universities receive about 60% of these funds, but NIH also puts a great deal of priority into stimulating the private market. The NIH in the United States has been scrutinised by the Congress as regards the benefits of NIH research investments. There are however many voices raised, which are positive to the support of more commercially applicable research instead of only supporting the expensive basic research conducted by universities.[119]

## 6.3 Investors

Another player in the biotech field is the venture capitalist providing the necessary fuel to keep the young and "research-intensive firms" up and running. Their contribution to the advancement of science is essential. These risk capital providers contribute not only with the capital necessary to keep the long-term and money swallowing projects going on, but they also provide valuable knowledge around these research projects, while closely monitoring the course of the project. In return they naturally want some reward. The remuneration they prefer is to administer the initial public offering (IPO) of the stock of the firm.[120]

## 6.4 Non-profit organisations

There are also non-profit organisations, for example important hospitals and non-profit institutes involved in the infrastructure of research in biotechnology. These institutes are conducting basic research and clinical development. The research role of these actors is similar to that of universities and government institutes. The routine has been that the non-profit actors are responsible for the initial and basic research, which has often been the case with universities as well and then they license their results to the DBFs. The DBFs then continue the development process and perhaps their work may even lead to the marketing of a product. Collaboration between the non-profit actors and the DBFs may be profitable to both parties in that the former of the two may provide help with the costly clinical trials and at the same time get access to promising new medical treatments.[121]

[119] Ibid. pp. 255-256.
[120] Ibid. p. 256.
[121] Ibid. pp. 256-257.

## 6.5 Pharmaceutical companies

The pharmaceutical companies are representing a global industry with high influence and power upon many different areas. They influence the world economy to a large part and their priorities are directly affecting important human rights, such as the right to life as expressed in article 3 of Universal Declaration of Human Rights. The pharmaceutical industry hosts both, important achievements in terms of intensive research leading to extremely vital drugs and at the same time they receive enormous profit for their work. Their interest in terms of the priorities in the research that they make is directly reflected in the commercial value of this research. The yearning for profit and efficiency in the conduct of research has however proven to be something that can cause big trouble to the pharmaceutical companies. They often concentrate on developing a few "blockbuster drugs" and manufacture large quantities of those particular drugs, which leave them highly dependent on a continuing success. The climate has become such as to favour merging and hence the pharmaceutical companies have become larger and larger in size. The pharmaceutical companies try to balance their activity by either outsourcing R&D or by acquisition of promising DBFs. None of these actions have proven very successful, but fact still remains that between pharmaceutical companies and young DBFs each hold knowledge that the other parties are in need of. The biotech company holds initial and basic knowledge, which is valuable for the pharmaceutical companies to be able to develop and manufacture the drugs. The large and experienced pharmaceutical companies on the other hand can provide knowledge in the carrying out of clinical trials and the process of manufacturing and are the holders of large sums to invest.[122]

## 6.6 More established biotechnology firms

The biotech industry is rapidly growing and more established biotechnology firms have only over the last decade managed to become somewhat of a spider in the web, since their representatives are collaborating with NIH, leading research universities and hospitals as well as non-profit making institutes or pharmaceutical companies. The collaboration, if this is the proper term to use, is different depending on what type of institution we are talking about. It may, for example, be a licensing agreement with a university or a non-profit research institute, a clinical study going on together with a research hospital and sales or distribution arrangements with a pharmaceutical company.[123]

[122] Ibid. pp. 257-258.
[123] Ibid.

## 6.7 Issues related to institutional infrastructure

It seems as if a growing problem is the lack of understanding between different institutions and their ways of negotiating and conducting research. Within the biomedical field of research there are numerous participants in the advancement of R&D. I have mentioned above the actors and where they belong in the infrastructure of collaboration and competition. Below I intend to explore why the different research and product development institutions are experiencing problems in cooperation and why the exchange of information is not without friction.

The global problem is of heterogeneous character, since the problems in cooperating arise between the different types of institutions. They are mainly having problems concluding deals with other participants related to the biotechnology and biomedical fields. To be more precise, the problems are connected to the incoming research tools from other sectors rather than the deals regarding their own research tools being outsourced to others. The key word is access and the difficulty to conclude deals to access certain research tools belonging to other players in different teams. The research tool may come from a university, a biotechnology firm or a pharmaceutical firm; it is the supplier's terms of exchange that the potential receiver feels are discriminating.[124]

University representatives claim that negotiating with other universities works well, while they find the private firms to be almost impossible to get along with. Their view is that the private firms are expecting too much in return for access to the research tools that they provide. The private firms in turn give a reply that the academic institutions, with referral to a past where they provided research solely to benefit the general public domain, are expecting access to an unacceptable extent. The problems may also surface between actors within the private sector respective in the public domain. A pharmaceutical company can possibly find it difficult to conclude a deal with a biotechnology firm, while they find much less difficulty in concluding agreements with another pharmaceutical company. The general idea is that the other party is asking too much and that their own work should be highly valued.[125] A general spirit of pure greed is reflected so to speak.

Universities are accused of expecting that private firms should be making their research tools free at disposal to them. They tend to forget that they are charging the private firms for the research tools developed in academic laboratories. The justification for the claims of the universities is that they are conducting research for more noble purposes, that is to say: academic purposes, while the private firms do their research for profit.[126]

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[124] *Expanding the Boundaries of Intellectual Property: Innovation for the Knowledge Society*, p. 235.
[125] Ibid.
[126] Ibid. pp. 235-236.

Private firms resent the halos that the universities are hiding under and claim that many important representatives of universities are far from saints. The representatives of those firms are providing examples of " indecent behaviour" carried out by important academic personas. First of all these representatives point to the fact that there are numbers of universities doing business with small private firms and the result might be that patented research tools supplied to university scientists sometimes end up in the hands of a commercial competitor. A general counsel of a biotechnology firm also insists "many companies will tell you that they've been burned by professors who've made deals with multiple companies."[127]

The competition and arguing continues, the academic research institutions with the general public as its recipient and the private firms with the important task of serving their shareholders. None of them are they eager to "give away" intellectual property. Complaints are also being raised about counterparts using research tools for other purposes than agreed and in doing so they are in fact making a breach to the license agreement or the Material Transfer Agreement.[128]

A representative of a major research university sees a danger in giving exclusivity to an investor. Simply by contributing a material the funding entity receives the intellectual property rights to all future products, to which it contributes. The person claims that this might stop the research institution from marketing and promoting any new products. It is emphasised that research conducted by a university, funded by the government, will be subject to demands of technology transfer, due to the rules in the Bayh-Dole Act. The result being that the very discoveries that the universities have made with funds from the government will have to be licensed to the private sector. The reason for this is that the government funding comes with an obligation for the universities to also promote the transfer of technology to the private sector.[129]

Companies criticize the universities for not understanding how to do business and for being afflicted with "cultural schizophrenia" in deciding whether they are academic institutions or business entities. In addition there are also many complaints on how the technology transfer offices of the universities are taking care of their outside deals. Lawyers and other representatives of actors in the private sector claim that these offices are understaffed, poorly organised and very conservative in their concluding of agreements. They also experience that the process of concluding a deal with a university technology transfer office is very slow and difficult. Still, perhaps the most constant complaint coming from both biotechnology firms

[127] Ibid p. 236 and footnote 40.
[128] Ibid. pp. 236-237. MTA stands for Material Transfer Agreement and it is a standard abbreviation for treating the terms and conditions for the access to a biological material of lesser value that often is not patented.
[129] Ibid. pp. 237-238.

and pharmaceutical companies is that the universities overvalue their own contribution and underestimate the risks and cost involved in commercial research and product development.[130]

## 6.8 Internal problems

There are also internal conflicts regarding intellectual property matters. Within universities conflicting agendas between scientists and the technology transfer offices is a hot topic.[131] The academic researchers on their hand are pressured to come up with scientific results and they are relying on quick access to research tools. From the view of the scientists the professionals from the technology transfer offices are hardly facilitating their task, even though this is in fact what they are hired to do. On the other hand the professionals from the technology transfer offices are of the opinion that it is impossible to cooperate with the scientists in whose interest they really are there. The top priority of the technology transfer offices is to license the university-owned inventions to the private sector and earn some money for the university in question. In executing their task they are eager to protect the intellectual property and research interests on a long-term basis. The deals that they are concluding are therefore of high importance and treated with caution. These professionals are annoyed with scientists failing to understand what they consider to be simple facts on how to conclude an agreement. At the same time the representatives from the technology transfer offices have to rely on the scientists to warn them about problems that may arise linked to the research they conduct and ultimately linked to the license deals negotiated, incoming as well as outgoing.[132]

There are similar problems emerging on other levels of cooperation. The interests of a particular faculty are not always the same as interests put in priority by the university it is representing and hired by. The faculty scientists enjoy according to academic tradition a great freedom in their conducting of research. In the private sector the scientists are often directly hired for a specific purpose and obligated to limit the research to that very area. If a scientist in the private sector changes employer he or she is normally not allowed to bring their research away from the former employer. Academic researches to the contrary often bring their research with them to the next employment relationship.[133]

A scientist moving from one faculty to another rarely leads to any problems, although the universities are as a rule entitled to claim ownership of an invention developed by the employee. The problems are more likely to arise if the scientist is stepping over to a private firm.

[130] Ibid. pp. 238-239.
[131] Ibid. p. 239.
[132] Ibid. pp. 240-241.
[133] Ibid. p. 241.

Normally, the outside providers of research tools are more inclined to form license agreements with the technology transfer office than with a specific scientist. The academic scientist is, hence dependent on the professionals of the technology transfer offices to be able to carry out research.

Even with a research climate getting harder and more competitive, the spirit of sharing data and advancements still exists among scientists, not only in the academic environment, but also in the private sector. It is a tradition that is not always of satisfaction to the professional lawyers and executives of the biotech firms.[134]

[134] Ibid. p. 242.

# 7 Identifying other issues

## 7.1 The research climate

I have discussed the structures in the exchange of information and the participants and I have also enlightened the different participants conducting research and exchanging results of their research. I have also mentioned the difficulties these institutions are experiencing in the process of this exchange, among other things due to the lack of similarity in organisation etc. Now I wish to further put these factors into perspective by clarifying under what type of climate the scientists of today are engaged in science and innovation. It is a commercial research climate remarked by less friendly sharing of achievements between fellow scientists.[135]

The number of different players in the field of bio-health related research has now increased, due to the rapid progress of R&D.[136] It is a factor that together with changes in patent legislation may have added to an increased commercial research climate. The universities are now seeking and obtaining patents on equal terms with genetic companies, pharmaceutical companies and biotech firms. The universities make use of technology transfer offices to patent intellectual property resulting from the research conducted by university faculty and staff. The effect is that the universities are becoming a part of the commercialised industry sector as business entities. These are the very same universities that a few decades ago were conducting research aimed at forming a part of the public domain without restrictions.[137]

Powerful vocabulary is applied when addressing the importance of the human health related industries and words such as biotech revolution, "gene giants" and multinational pharmaceutical companies come to mind. Jeremy Rifkin, born in the United States, economist, activist and author of the book "The Biotech Century: Harnessing the Gene and Remarking the World"[138] is convinced that the futurists are presenting an image of the twenty-first century that is too limited. He instead labels our century the "biotech century". It is a fusion between the knowledge in the development of "intelligent" computers and genetics, which creates a foundation for a powerful biotech force economically as well as on a scientific basis. The computers are being used to decode the human genome and to organise it so that it can be used to provide information about hereditary diseases, for

[135] *Intellectual Property and Human Rights*, WIPO, Geneva 1998, p. 142.
[136] Eisenberg, *Bargaining over the transfer of proprietary research tools: Is this market failing or emerging? P. 226.*
[137] AgBiotech Buzz: Intellectual Property, Volume 3 Issue 1, March 3, 2003, *Who Owns That Gene? AgBiotech and Intellectual Property*, http://pewagbiotech.org/buzz/print.php3?StoryID=91, 24/11/03.
[138] Tarcher and Putnam, 1998.

instance. Multinational corporations are creating giant life-science complexes with the wish to govern a "bio industrial world". There are many objects that can generate profit based on a shorter term, such as new plants, animals, pharmaceutical products etc.[139] With the knowledge conceived of the DNA molecule and its structure it is now possible to trace and detect sick genes. The ability to create medicines and vaccines through the genetic modification of microorganisms also has great consequences.[140]

There is a risk in the commercial turn that research has taken within the field of biotechnology. Patens are stimulating the will to innovate and invest, but the health-related research forums are directed towards commercially profitable diseases, such as cancer and different heart conditions. More rare diseases, such as sleeping sickness, Chagas or Leishmaniasis, which only inflict poor people risk to be overlooked. These types of rare conditions are not likely to create a high profit, so it serves at nothing to take out a high price for drugs treating those conditions to generate R&D.[141]

Rifkin is worried about the consequences of letting the market place and its consumers set the standards because of ethical risks as well as possibly harmful social and environmental effects. He poses the question if we really want a world where the creation of "the perfect baby" is the goal with research?

### 7.1.1 Secrecy and withholding of data

The issue of secrecy is a factor, which may delay progress of research in certain fields. There is evidence suggesting that research is delayed in the biomedical sciences, at least before its publication. The reasons for this are quite unclear.[142]

The defensive action of withholding data, research materials and research results is according to reputation more common in genetics and especially human genetics, than in other fields. The explanation for this is simple. It may be necessary to wait with the sharing and publishing of data as a part of the process of applying for a patent. A commercial R&D partner also demands delays in the publication of research data and results.[143]

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[139] Jeremy Rifkin: *fears of a brave new world*, interview by Amy Otchet, http://www.unesco.org/courier/1998-09/uk/dires/txt1.htm, 8/3/03.
[140] Nau J-Y, *Un extraordinaire outil de recherche et d'éxploration*, http://www.lemonde.fr/imprimerarticleref/0,5987,3244---316054,00.html, 15/04/03.
[141] http://www.msf.org/content/page.cfm?aricleid=ADA6508E-8907-4010-98650D3E93..., 8/12/03.
[142] http://www.oecd.org/dataoecd/42/21/2491084.pdf, pp. 12-13, 5/1/04.

[143] Ibid.

## 7.2 Patenting genetic material

Discoveries and information do not in themselves constitute patentable subject matter. The information relating to gene sequences or to gene applications, which result in the expression of attractive traits will not by itself form patentable subject matter. Indirectly, gene sequences and interactions could, however, form patentable subject matter, since the application of certain desirable gene sequences and interactions in a product or process is eligible for protection by the patents. In reality it is thereby possible to obtain patent protection of gene sequences and interactions by obtaining patent protection for all possible known applications of the information relating to the gene sequences and interactions. The actual grant of such patents presupposes that the patentability requirements are met.[144]

"The biotechnology industry has invested hundreds of millions of dollars in the development and commercialisation of drugs, diagnostic devises, research tools and genetically modified crops and animals, resulting in products that today garner $27.6 billion in annual revenues".[145] Still there are some people, who are concerned that biotechnology patents do constitute an obstacle to research and innovation rather than the opposite.

If a company owns a gene or a genetic sequence, interested researchers have to pay a royalty and ask permission from the owner to be able to exploit the patented subject matter. Otherwise, they risk a lawsuit for infringing the patent.[146] Hence, we are facing a situation, where patents may block or at least delay important research. Such was the case when a private company Myriad Genetics found two genes for breast cancer BRCA 1 and BRCA 2. What they did was finding two genes in which mutations would indicate a high risk for developing cancer. Actually 50-60 % of the persons with mutations in those very genes would probably be sick of breast cancer before the age of 70. It is a number to be compared with that only 5-10% of all breast cancer cases are determined to have a genetic link. Myriad Genetics was the patent owner of the two genes and the process how to determine the level of mutation causing cancer.[147] The consequence being that researchers with the need to use those genes as a part of their work would have to conclude license agreements and pay royalties to the holder of the patent. Now research is being conducted in Sweden linked with the University hospital in Lund to try and detect a third gene, which indicates breast cancer. It is of great weight to find a gene that can be used when bargaining for easier access to the other breast cancer indicating genes BRCA 1 and 2.

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[144] *Biotech patents: Equivalency and Exclusions under the European and US Patent law*, p. 6 and footnote 51.
[145] http://pewagbiotech.org/buzz/print.php3?StoryID=91, 24/11/03.
[146] Ibid.
[147] http://gslc.genetics.utah.edu/units/newborn/infosheets/BRCA.cfm, 15/12/03.

A hazard with the issuing of patents related to the human genome is the proliferation it causes. The patents are fragmentary and large in quantities and this makes it possible to conduct research without getting several different licenses,[148] a phenomenon that is referred to as "patent thickets".[149] Just to put it in perspective, in February 1998 the USPTO received more than 5000 applications for patents on whole genes and in 1500 of these cases the result was positive for the patent applicant.[150]

Another line of discussion on the patenting of DNA concerns the risk that overly broad patents are blocking important research data from being used by other scientists. It is a possibility that patents on foundational discoveries[151] may limit or prevent the use of other scientists. This is not a real problem if the invention is generously licensed.[152] It is feared by researchers that patents on genes that indicate a disease could have a blocking effect on further research connected with this disease. In most cases however, the holder of a crucial patent, is more than willing to share the patented subject matter through license agreements.[153]

It has been argued from several different directions that the human genome should be in the public domain and not being bargained over like propriety. Protests have come from as different corners in society as scientists, religious groups, politicians and last, but not least, the general public. It is argued that the human genome and life in general should be seen as belonging to the "common heritage of mankind" and should hence not be patentable. The UNESCO Declaration on the Protection of the Human Genome and Human Rights adopted by the UN General Assembly in 1998 support this thesis.[154]

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[148] *Intellectual Property and Human Rights*, p. 145-146.
[149] http://www.oecd.org/dataoecd/42/21/2491084.pdf, p. 61, 5/1/04.
[150] *Intellectual Property and Human Rights*, p. 143.
[151] Foundational discoveries are early discoveries that are of particular importance since; the continued research in a field may depend upon that very discovery. http://www.oecd.org/dataoecd/42/21/2491084.pdf, pp 12-13.
[152] Ibid.
[153] Ibid.
[154] Ibid. pp. 146-148.

# 8 Concluding analysis

Hans Blix, the former chief of the United Nations Weapon Inspectors, mentioned during a speech he held in the AF-building in Lund on December 8th in 2003, that the means for protecting patents between countries are more developed than the means available for protecting a country from being attacked by another state. In my opinion this is a sign of the commercial times we are living in.

I have mentioned the Bayh-Dole Act and the reform, which took part in the US more than two decades ago resulting in the universities also patenting their research and discoveries. This legislation may have had some contribution to a research climate with a lesser will to share the knowledge as well as infrastructure difficulties in the sharing of advancements. The reason for these claims is that the academic institutions were given the opportunity to patent their inventions. The academic institutions are now participants in the patent race. It is when making such claims also important to take into account the reality in which the different institutions engaged in research and development of the bio-health related industry are acting. It is an industry with genetic giant corporations as well as both established biotech firms and multinational and influential pharmaceutical companies. If all the research conducted by universities, governmental institutes and the NIH was to be let free in the public domain the other hungry participants in the industry would file patent applications leading to the necessity of having to ask permission of the giant corporations and pay large amounts in royalties to be able to advance in important research. The companies are filing patent applications, which are as broad as possible to cover large areas of research and development. In the public interest and for the sake of maintaining a balance between research conducted for the sake of the public health and research conducted with mainly profit as the main goal, it may be necessary for the federal state to be able to obtain patent protection. The NIH in the US is exercising the method of strategic patenting to promote public health and the spreading of research results while at the same time encouraging competition.[155]

The expanded patent criteria has lead to that genetic material and its different applications, since quite a few years may constitute patentable subject matter. It is according to legal experts an established matter.[156] The consequence should be an interpretation by the patent offices and ultimately the courts that is realistic and progressive. However, it is in my firm opinion that the practice of these two institutions must not depend on a lack of scientific knowledge in the areas concerned. We have seen a few examples in history where the practice of the patent offices and the courts have

[155] http://www.oecd.org/dataoecd/42/21/2491084.pdf, 5/1/04, p. 53.
[156] Ibid. p. 10.

opened up to a massive number of patent applications that should never have been filed if it were not for those very decisions.

The necessity of patents as regards the health-related industries, such as biotechnology and the pharmaceutical industry, is however obvious. The intent is to stimulate R&D and as earlier mentioned in this thesis, it has proven also to be the actual result.[157] However the patent institute is to be seen as a contract, where the private person is stimulated to invent by the possibility of obtaining intellectual property protection and where the benefits of the invention should also ultimately benefit the general public.

Problems come to light due to the enormous commercial powers of the industries related to biotechnology and foremost the pharmaceutical industry, which has more direct effect on human health and with the possibility to deny people of their fundamental human rights of right to health and right to life.[158]

On January 24-25 in 2002 the (OECD) working party held an expert workshop on the subject "Genetic Inventions and Intellectual Property Rights and licensing". The purpose with the workshop was to try and determine the impact of patents on genetic inventions and technologies endowed with DNA patents and also to examine the challenges they pose to scientists, representatives from the industry as well as medical practitioners.[159]

I intend to illuminate some of what was concluded during this important workshop. I will start by referring to an important statement that was made under this workshop. The general idea of this statement is that the issue is no longer whether "gene patents" should exist or not. The issue is: how the patents are used and licensed. It is of importance to try and determine the existing problems relative to patented DNA fragments and to attempt to find remedies, to make a better system.[160]

It was concluded that the licensing of genetic inventions was not something that could lead to an economic breakdown. Nothing in the available evidence that had been examined would suggest that this could be the case. The concerns of patents blocking research information or over-fragmentation, was according to the experts very much exaggerated, at least in-as-much as they would affect the economic revenues of the bio-pharmaceutical industries. On the other hand, in specific areas of research there is evidence of problems linked to the number and breadth of patents. The phenomenon of "reach-through agreements" is a big concern that may need government attention. It has become an issue of worry, since there has been an increase in the use of reach-through claims in patents over the last

[157] More information about the case Amgen v. Genetics under headline 7.1.
[158] The right to life, art 3 Of UDHR, right to health, art 15 of the ICESCR.
[159] http://www.oecd.org/dataoecd/42/21/2491084.pdf, 5/1/04, pp. 3 and 77.
[160] Ibid.

few years, especially involving the use of research tools protected as intellectual property. The reach-through clauses in licensing agreements may in the long run affect the development of pharmaceuticals in a negative way and contribute to "royalty stacking". Empirical studies have also indicated problems emerging regarding the access to diagnostic genetic tests.[161]

The experts of the workshop state that there is a gap between the general opinion concerning the patenting of genetic information and the position taken by the legal and industry representatives on the subject. The public concern is mainly linked with ethical issues concerning pharmaceuticals or cloning. However, experts hold also different opinions on the tolerable scope of patent claims and whether some of the gene patents should be allowed or not. DNA patents are legally allowed and there are consequences attributable to the rights that they give to their owners. The experts of the workshop emphasised the vitality in discouraging more extreme license practices. Different surveys presented suggest that for a scientist to have freedom to conduct research without patents constituting obstacles, there are in fact many patents to be dealt with. Public research entities sometimes ignore these patents if the research that they are engaged in is not for commercial purpose. Their justification for these questionable actions is that they, as public research organs, are entitled to an "informal research exemption". The group of patents that are likely to prevent public access or prevent a pharmaceutical product from being put on the market is limited.[162]

The group of experts from the "Workshop on Genetic Inventions, Intellectual Property Rights and Licensing" discussed furthermore suitable remedies to the above-mentioned issues and challenges. They emphasised at the same time the importance in that those very remedies should be in tune with a patent system that should be very adaptable and in tune with science and innovation. The remedies, or solutions that they discussed were the following: monitoring, research or experimental use exemption, a self-regulatory system, change in the administrating of patent applications, regulatory solutions and guidelines issued by the government for good patent practice.[163]

The expert participants in the workshop were not intimidated by the fact that patents are issued on genetic material necessary in the biotechnology, biomedicine and pharmaceutical industries. According to their conclusive opinion, which was based on their knowledge as experts and the evidence presented at the workshop, the patents did not cause any real economic damage.

The fact that it is necessary to obtain a license to use the patented genetic material does not mean that it is an obstacle that is high enough to prevent

[161] Ibid. pp. 77-84.
[162] Ibid.
[163] Ibid.

new pharmaceuticals from being introduced to a commercial market. In considering the effects that the patents and the licenses may have on research conducted in the bio-health related research and development. From another angle, the answer is quite possibly different. Research and development carried out on a daily basis face the trouble of dealing with the lack of access to research tools and the issues around reaching agreements with other institutions. It is not the question of terminating the system for intellectual property, because I genuinely believe in the patent institution as a good path to stimulate science and innovation, it is more an issue of scrutinising the proportions of the possible negative effects that it can bring. The intellectual property protection system has obvious commercial links and its existence is of great economic value. It is, however, of weight that a balance is maintained, so that the general public and consumers have the possibility to reap the fruits of research and development. It is also of clear importance that also the consumers, authors and inventors in the developing countries are able to benefit. I wish to see a balance between private and public interests. I believe, that a patent system that is too much a part of a free market will create discrimination. It is hence necessary with intervention from the government to direct research toward the more rare diseases. The possibility for the least developed countries to import or manufacture generic drugs is also of great significance. It must be kept in mind that, while the proprietary and economic rights are being safeguarded with a patent, that very institution for protection is likely to have social and human rights related consequences. The patent system is commercial to its character, but it can have serious social and human rights related consequences. The patent system when exploited as the powerful economic tool it is, may have horrible effects.

It is still very difficult to be granted patent protection for an invention. The concept of what is an invention has been broadened to be in tune with science. To me, the word invention has lost some of its exciting and romantic glow. In most cases it is no longer an object useful and widely appreciated by the people, such as a telephone, a vacuum cleaner or a steam engine. This development is understandable when considering the productive centuries that have passed. Great things, both in size and in terms of the number of consumers profiting, have already been invented and manufactured. It is only natural that our current challenge is of miniscule size. The importance of what is achieved is still great.

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