Dangers in the Biotech Age

– the truth about Biotech Rights

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1. Introduction

Biotechnology is making astounding progress. In recent years cells, living organisms and substances from living organisms have been used in the development of many different products such as pharmaceuticals, microorganisms and treatment methods, as well as in the genetic alteration of animals and plants, to an ever increasing extent. The human genome, i.e. the genes, has already been mapped and by this time the map of the human proteins, the proteome, is steadily developing. The opportunity to patent genes and gene sequences has been utilized to a large extent and still is. Genetics is used in both basic and applied research and is in the present-day situation practised within medical services, agriculture and in environmental applications. But still biotechnology is in its initial stages of development. The opportunities presented by genetic manipulation are next to indefinite and will give rise to numerous useful and necessary products and treatments. The novel technologies and products have the ability to alter the fundamental conditions for society in a revolutionary way. Genes, proteins and other basic biological building blocks have become very lucrative commodities. On account of this, the life science studies that were previously performed primarily at universities have been assumed by the private corporations to a large extent.

But patents on genes and other basic biological products and processes do not only promote advances within the biotech sector. The genetic inventions are on the contrary associated with important problems which negatively affect research and obstruct or even block future development work, and the limited access to the technology causes an erosion of the public interests. These difficulties arise on account of the broad protection that is granted and the monopoly power that these patents bestow. Problems also come up because numerous of the patents granted lack medical and scientific merit. As I will demonstrate onwards, researchers' access to information, research tools and other materials necessary for further development risk being restricted on this account. The patent owners are able to misuse their monopoly rights and can prevent research work aimed at finding cures for diseases or for developing gene-therapies and even prevent doctors from screening patients for disease carrying genes. The limited access to genetic information thus brings about delayed progress, increased transaction costs and restrict the publics' access to medical treatments and pharmaceuticals.

The patenting of basic biological building blocks and living organisms have been controversial from the start and many call for bans on further gene patents. Numerous people also object to the present system by maintaining that gene sequences are discoveries and not inventions. They look upon the genomic information in plants, animals and humans as information that is just as fundamental as the periodic system, and that it is wrong for a predominant part of the information to be owned by different companies and public institutions that consequently gain from them. The fact that the patents are based on basic data that to a large extent has been produced by government funded research reinforces the arguments that further developments should be kept in the public domain and form the foundation for future development, or else the taxpayers will be cheated of research results they have funded. Others oppose patents on genes and other biological compounds based upon principles of human rights and human worth. They are apprehensive of the future possibilities and consequences that may occur when we start tampering with our evolutionary future. They believe that the patenting has already gone too far and will inevitably have devastating consequences.

The biotech industry maintains on the other hand that patent protection is of vital importance. The technological change in this sector is rapid and research and development is very important to all companies. Much of the research is also very expensive and the industry obviously wishes to be able to retrieve the costs and make a profit. The industry and the legislator generally consider the biotech patents to be necessary incentives for technological innovation and maintain

that they do not differ from regular patents. Notwithstanding these facts the existing regulatory structures are not satisfactory. They were created by weighing conflicting interests and priorities and are indeed compromise solutions. The present system has to some extent gone awry and risk becoming even more distorted if measures are not taken without delay. Economic self-interests direct the development to an ever increasing extent and even those who used to perform research for public interests, such as universities and other public institutions, are today guided by short-term financial goals. A change in the current system is thus called for.

At the moment there is no agreement on how the problems associated with gene patents should be minimized and to what extent patent protection ought to be granted basic biological processes. Hence there is a need for authoritative reviews and critical scrutiny of the present systems. Current laws and regulations are ineffective and lack legal merit. Moral and ethics are furthermore completely neglected in the procedures. The public and political debates on the issues have not been able to keep up with the development and the appropriate measures have not been taken. The general public are furthermore not conscious of the extent to which their daily lives are, and to an ever increasing extent will be, affected by present developments. Thus there is a long-felt demand for information on these issues. Because the effects of modern biotechnology will be enormous the public must be engaged in the discussions and given a voice as to the future of biotechnological development, and that voice should be listened to.

1.1 The purpose of this paper

The aim of this paper is to enlighten the reader on the multifold problems and dangers that derive their origin from patents on genes and other basic biological products and processes. I will thus make an examination of the current system to see whether the instruments of control are well adapted to their purpose and promote scientific progress and continuous advancements or if they go beyond the law's initial intentions and jeopardise and inhibit progress, stifle development of improved and more cost-effective therapeutics, treatment methods and patient care.

I will help the reader gain knowledge on the biological background and the regulatory framework and I will examine the scope and goals of the existing legislation for an additional understanding of the problems faced in the present-day situation. I will also examine the ethical, social and scientific aspects that follow from the commercial exploitation of genetically based inventions. My hope is that the paper will serve as a basis for further discussions that in turn can lead to the appropriate measures being taken.

1.2 Limitations

The aim of this paper is to promote discussion and a greater understanding of the problems at hand and to point out weaknesses and problems that the current system originates. It is not my objective to solve the problems per se or to cover all possible aspects of the patenting of biotechnology.

I have excluded agricultural biotechnology, industrial and environmental products and services, and restrict my investigation to only include the American and European legal systems.

2. The Genomics industry

For the average person versed in the law, biotechnology is a complicated and foreign subject matter. For you to understand the issue at hand and to spark your interest I will start with an introduction to the genomics industry. It is important to comprehend the overarching matters or else it will not be possible to perceive the importance of the issue at hand and the consequences will be less obvious.

Most people are unaware of the technologies being developed today and the enormous potential and risks they bring with them. Media is also showing a surprising lack of interest. Hardly any in-depth examinations are made and the positive image that has been marketed by industry and the governments stand unchallenged. The only subject that has been discussed and criticized is the cloning of humans and animals and that debate has almost vanished. The general public thus form the idea that biotechnologies do not involve any threats whatsoever. The impression I have gotten while writing this paper is that the people that possess sufficient technical knowledge disregard the fact that any obstacles or dangers can be derived from the technology, and the people that do not have enough knowledge and information disregard it because they are not aware of what the new technologies involve and the development it originates.

2.1 Present technology

Biotechnology has many industrial applications. Our knowledge and technical skills has helped us finding drugs and vaccines for cancer, Alzheimer's disease, diabetes and pneumonia among other things. The most well known application is probably the methods for diagnosis of particular genetic conditions. With these tools the patterns in which DNA fragments are built can be studied and it is possible to detect chromosomal defects, to see whether the fragments are rearranged or swapped between chromosomes et.c. These defects indicate e.g. Down's syndrome and other predispositions to various diseases.

There are also biomaterials for medical applications being made. Materials suitable as replacements for damaged human organs or tissues, prosthetic devises such as artificial heart valves and a device that facilitates blinking in patients suffering from facial nerve palsy have amongst other things been developed. Biomaterials can also be used for controlled drug delivery. A well-known example of this is how nicotine-patches deliver drugs through the skin by diffusion. Within this branch of medical research investigation of possible new treatments for AIDS, bacterial and viral infections and delivery of dopamine into the brain of Parkinson's patients are being done as well[1].

It is possible to change the natural properties of living organisms as well. For instance, US researchers have altered the bacteria that normally damage our teeth. They have the same properties as the regular bacteria except they do not produce the acid that damage the teeth. When introduced into the mouth they eliminate the natural bacteria and take their place. So far they have only been tried on animals, but it is envisioned that they shall be sprayed into the mouths of all one year olds and, voi'la, no more cavities or toothaches.

Transgenetic animals are also being developed. They are animals that have a permanently altered genetic profile. To create one of these animals, genes are transferred to a fertilized egg. A minimal amount of DNA is transmitted into the egg where it will hopefully link together with the DNA there. If this step is successful the egg is transferred to the uterus of a living animal where it will continue to develop like any other foetus, with the exception that it has been modified to

[1] Biomaterials Facilitate Medical Breakthroughs, Jennifer Ouellette, The Industrial Physicist

have certain traits that the natural ones do not have. It will for instance grow faster or be resistant to some disease. By using this technique it is imagined that it will be possible to cure certain hereditary human diseases as well.

Another startling idea is the notion that it will be possible to produce pharmaceuticals in animals. Animals will be genetically altered so that their milk will contain large amounts of certain proteins that will be used as medicine. Insulin could for example be produced this way. Instead of taking an insulin-shot a patient will then drink the milk and get the medicine into its system that way. This genetic-farming is from what I understand not too far away.

Food is also being modified to contain less fat, sweeter taste or to contain more nutrients and it is common to make genetically modified plants. An example of a genetically modified product is the salt-tolerant tomato. It was developed by adding active copies of a single gene that is normally inactive and that gene encodes a protein that shuttles sodium into sacs inside the plants cells, protecting them from salt damage. These tomatoes are supposed to convert barren land into fertile soil. It is also worth mentioning that it is possible to use biotechnology to develop environmental applications such as the production and replacement of certain chemicals and to purify water, air and soil.

2.2 Increased patenting

When discussing the genomics industry it is necessary to make a report of the Human Genome Research Project (HUGO). This project was designed to map the exact nucleotide base sequence of the entire human DNA which contains approximately 35 000 genes. The goal was reached in April, 2003 and the sequence covers 99 % of the human genes and has an accuracy of 99,99 %[2]. All results have been published in public databases on the Internet and are made freely available. Thus the scientific community can use this information without any restrictions or limitations and develop them further into patentable inventions. The project was made possible due to extensive funding from the American, French, Chinese and British Governments.

But not all information generated within the genomic industry is made available this way. The international corporate strategies involve patenting of all basic and applied research results to an ever increasing extent and the public institutions are influenced by the market objectives and have reoriented much of their research towards proprietary research. This has raised the number of patents significantly. The trend is reinforced by the current patent policies. As I will discuss in more detail onwards the customary requisites for patent protection have been adjusted to remove discrepancies in the rules and regulations with the aim to promote innovation in the biotech sector. But genes and other basic biological products and processes are different from regular inventions and will affect future development to a larger extent than other patents have capacity of doing. The extensive patenting in the biotech sector is thus associated with important problems which affect innovation, competition, accessibility and diffusion of technology.

When discussing genomics the first thing that comes to most peoples mind is Dolly the cloned sheep and designer babies, but this is not the only issues that ought to be debated. Soon biotechnology will affect everyone's lives and the questions of who should have title to our cells and genes, the delimitation between inventions and discoveries, the breadth of the legal monopolies and what development that will be beneficial to society as a whole must be discussed to an increased extent.

[2] International Consortium Completes Human Genome Project, All Goals Achieved; New Vision for Genome Research Unveiled, DOEGenomes.org

The largest hindrance to development that the current system originates is the lack of availability to genomic inventions, i.e. genes, gene sequences, proteins et.c. The patent owners are able to prevent other researchers from studying fundamental and basic knowledge and develop it further. It is obviously important that commercial companies are given title to their inventions and that the patent system enables and rewards costly and time-consuming innovations, but it is increasingly necessary to evaluate the costs of the patent activities and their impact on future research and innovation. Today the policy instruments are ineffective both economically and legally. The impact of the biotech patents need to be carefully and substantially examined and a fine-tuning of the patent system is an imperative necessity if an effective allocation of the finite number of genomic resources is to be achieved.

As our knowledge grows, amazing new products and treatments will continuously be developed and they will increase our wellbeing and make our lives easier. But the developing technologies also involve immense risks for humanity. The same knowledge that is used to find cures for serious diseases can for example also be used to develop designer diseases that can wipe out a particular family. At this very day designer diseases that target animals are being developed[3]. A self-spread genetically modified virus that affects the reproduction in mice is for instance being developed in Australia. When a mouse is affected by the virus the immune system produces anti-bodies to block reproduction thus making the mouse sterile. The virus may possibly be fit for use in Australia seeing that mice are introduced and not part of the natural food chain there but the drawbacks still outweigh the benefits. Firstly it is not possible to withdraw the virus once it has been released and secondly you have no control over the virus once it has been released. It could possible mutate and/or jump to other species for instance, and if the virus spread to other parts of the world mice that are an imperative part of the food chain would be exterminated[4]. Safety can hardly be entirely assured and projects like these can prove to be ravaging.

As a result, we do not only have to develop legally, politically and economically acceptable policies for the patenting of biotechnological products and processes, they also have to be ethically, socially and morally acceptable. To be able to work out suitable formulae it is necessary to analyze the context in which the patents work as well. In this paper I will investigate the dangers that the current system originates and I will also address some of the wider public concerns.

[3] Pest Animal Control CRC, Homepage
[4] Designer Diseases by Claire Bowles, New Scientist August 2003

3. The ABC's of Biotechnology

The discovery and determination of the qualities of genes and proteins make up the bulk of all biotech research. I will continue with a short examination of how living organisms are constructed and how genetic engineering works since this will help you to understand what is really being patented and why these patents have the effects that they do.

The hereditary elements, the genome, are complicated macromolecules containing DNA. The DNA molecule contains thousands of genes. The genetic information in these is the blueprint that determines when and how cells and proteins are created and how they are arranged. All cells contain the same genes but depending on the current function of the cell, different genes are expressed which gives it different properties and it will also produce different proteins. There are thousands of different proteins and it is actually the proteins in a cell that determine what that particular cell will look like and what tasks it will perform. The proteins are the actual structural and chemical building-blocks and as such, the active elements of all living organisms. This is the way your hair colour, the placement of your heart, the shape of your toenails, if you have any hereditary diseases et.c. is determined[5].

Not all genes in the DNA strand have a known function, as much as 90 % of the hereditary factors are composed of non-coding DNA[6]. To a great extent the DNA found in different living organisms are exactly alike. Hence humans share a great deal of our genes with bacteria, plants and animals.

The DNA sequences are built up by sub-units called nucleotide-bases. The bases are bound together in a long chain. There are four kinds of bases and they are called Adenine, Guanine, Cytosine and Thymine (A, G, C and T) and the different DNA sequences are thus built up by different combinations of these bases. The sequence of the bases is the foundation for a code, like a genetic language. The nucleotide-bases are positioned in three-base sequences and the term for them is Codons. They can be compared to a word containing three letters. These words specify how a particular protein shall be constructed. Each word corresponds to a particular amino-acid in a particular protein. The order in which these "words" are positioned thus determines in what order the amino-acids shall be placed. Since there are four different nucleotide-bases there are sixty-four possible combinations of the three-base Codons, but there are only twenty different amino acids that make the proteins in the human body. Hence the Codons can generally code for more than one amino acid. This obviously complicates matters a bit when we want to identify the DNA-sequence for a protein. In addition different genes code for different proteins and many of the genes code for numerous similar proteins which makes it harder to identify the corresponding DNA sequence.

Today we pretty much know where the different genes are located on the DNA chain, but we still do not know much about their function. But we do know that the different DNA sequences code for a large amount of proteins. Currently researchers believe that there are at least 100 000 primary forms of human proteins, and numerous additional modifications of these[7]. If the modifications are included there are probably tens of millions of different proteins. Obviously it is a great challenge to describe the function of the genes and proteins, but efforts are made worldwide. The proteins are of particular importance since it is their activities in our bodies that determine how we feel and if we are well or sick. As a matter of fact, 90 % of all pharmaceuticals target proteins[8]!

[5] The National encyclopedia, Homepage
[6] The National encyclopedia, Homepage
[7] Vad generna egentligen gör– Protein-koden kartläggs av KTH , Homepage
[8] Kroppens proteiner kartlagda av forskare, Göteborgsposten 2005-03-09

3.1 Genetic engineering

Modern genetic engineering was established during the 1970s and 1980s. One of the most important advances was the hybrid-DNA technique. The technique makes it possible to transfer or exchange selected genes between two organisms or even add new genes. Previously mutations in the genes could only be made randomly by using radiation or certain chemicals, but today it is possible to make specified interferences in the genes due to the hybrid-DNA technique. The technique has for example made it possible to develop growth hormone against dwarfism and insulin against diabetes and it is continuously used to develop additional cures and remedies. The technique will in the future also make it possible to repair genetic defects that cause diseases and defects in humans. If an individual has a genetic defect it will be possible to exchange that particular gene. The altered genes will in this case not be transferred to descendants as is the case when sexcells are altered[9].

Above I demonstrated that different genes code for different proteins and that many of the genes code for numerous similar proteins. To identify a specific DNA sequence one must take two steps. The first thing that is done is to create a "library" of the DNA sequences that code for proteins in a specific cell. This is done to reduce the number of sequences. The second thing to do is to design a probe that will tie to the DNA sequence of a specific protein. The probe is a fragment of DNA produced by genetic engineering and is designed to bind with the desired complementary DNA sequence. It is only possible to do this if the amino acid sequence of the protein is wholly or partially known.

When a gene has been isolated this way it is possible to produce DNA artificially owing to the PCR-Method. The technique enables us to manage the genetic processes in detail and it is possible to select certain parts or a certain gene to multiply. Whole populations of a certain gene can be produced and you end up with what is called cloned DNA. The cloned DNA is used in research and in the production of pharmaceuticals, vaccines et cetera.[10] The process also makes it possible to produce large quantities of a selected protein. The process is e.g. used to make insulin for diabetic patients[11]. Lastly the method can also be used to identify pathogenic mutations as well as individuals in criminal investigations. The technique supposedly makes it possible to produce better pharmaceuticals than previously. Earlier, substances from animals and dead or living people had to be used to make the medicines. This gave rise to problems such as an irregular supply of material and a risk that the substances carried disease[12]. By using artificially produced substances it is possible to circumvent many of these problems.

Another important development is the process by which it is possible to "cut" pieces of DNA and "glue" them together with other DNA thereby creating hybrid-DNA. It is various enzymes that do this job and make it possible to transfer a gene from one organism to another. The transfer is facilitated by adding a vector to the transferred DNA. Vectors are viruses or DNA that has a natural ability to transfer itself to other organisms.

[9] Hybrid-DNA, Michael Bonnier, Homepage
[10] The National encyclopedia, Homepage
[11] Intellectual Property Rights in Biotechnology: Addressing New Technology, Arti K. Rai page 3-4
[12] The National encyclopedia, Homepage

4. The patent protection

All of the discoveries mentioned above are important and also extremely profitable for companies. Today it is possible to patent partial gene sequences, whole genes and the protein that these code for providing that they have not been previously isolated and described. A gene that is isolated and given a task as a pharmaceutical- or diagnostics tool can also be patented. The vectors that facilitate the transfer of a gene from one organism to another are also being patented alongside the processes that are being used when organisms are modified. The modified organisms themselves, such as microorganisms, cells, plants and animals, can also be patented. Lastly, all uses of the above can be patented as well. It is for instance possible to patent methods for the production or analysis of a protein and the use of a protein in an analytical method or a pharmaceutical preparation, as well as different kinds of diagnostic tests, therapeutic proteins, applications for a proteins function, procedures for gene therapy and research tools[13].

Today biotechnological inventions are patented intensively. The primary reason to acquire patents is obviously to protect technologies, but it is far from the only reason. A large patent portfolio is considered to be an indication of a strong company and numerous patents make it easier for a company to attract venture capitalists and collaboration partners. Patents do not necessarily have to be profitable it seems, quantity is more important than quality in many respects. Small and medium sized enterprises are particularly dependent on patents. The patents might be the only valuable assets that the companies have, and if they are to enter into alliances with other companies or share R&D costs patents are necessary. The drawbacks, i.e. the costs of patenting and the disclosure of technical information, are generally considered outweighed by the benefits. Companies derive great advantages from cross-licences and the ability to attack and injure competitors. Many times the blocking of competition seems to be the primary object, not the protection of the technology per se.

It can seem rather remarkable that genes can be patented at all. Despite the fact that gene patents have been granted for over twenty years there is still tension between what ought to be patentable and what should only belong to nature itself. As we will see shortly genes are considered comparable to chemicals and are as such patentable subject matter. But genes are also information carriers, a fact that clearly distinguish them from other chemical compounds and it is this duality that makes it hard to justify the patenting of genes.

For many years there has been a heated debate over whether genes and other basic biological building blocks ought to be patentable and whether these patents stimulate innovation or have a detrimental effect on progress. The industry argues that without the possibility to patent genomic inventions no companies would invest the time and money needed for innovations because of the high risks and costs associated with development work in this sector. The patent system was introduced for this specific purpose, i.e. to stimulate innovation by granting inventors protection and exclusive rights. By allowing genes and other biological materials to be patented the present system gives the patent owners a total control over fundamental biological products and processes for twenty years. The owner might decide to share his patent with the rest of the world and allow e.g. universities and competitors to use the patent in their research work. But the owner might just as well prevent others from using it and is able to block future research, raise prices and restrict access to drugs and treatments. Some patent owners even prohibit use of their patents when no commercial gains are involved. If and when these latter scenarios occurs the second purpose of the patent system is impossible to fulfil. The patent system was introduces to facilitate distribution of technology and knowledge as well, and aims to promote future product development to the benefit of the general public. Genomic patents could be hindering

[13] Genetic Inventions, Intellectual Property Rights and Licensing Practices, OECD Paper, page 28

development efforts and stifle innovation. Thus there is a built-in conflict of interests in the system, the interests of the general publics vs. the interests of the patent owners. The legislators have weighed these priorities and made a compromise solution. In other lines of business the system works well. Important technical information is disclosed to the public and stimulates further research, but that is not necessarily the case within the biotech industry.

Lately there seems to have been a shift in priorities that have given rise to even more debates. The interests of the general public have on the whole been neglected, and the interests of the patent holders have been promoted. The European Court of Justice has on a few occasions' even defined patent rights as solely being an economic reward for the patent owners[14]. The court has also claimed that the patent system should primarily be aimed at enabling patent owners to prevent others from using an invention and to allow the owner to get compensation for their efforts[15]. It is doubtful whether this approach will stimulate long-term technical and economic development. It is particularly troublesome because the technological advances in biotechnology are mostly generic[16]. Differently put, the advances arise through a process where existing knowledge is further developed, combined in new ways or applied to new problems and result in new discoveries. If access to important biotech tools and information is restricted it will hence affect further innovation negatively.

These facts have led to a significant opposition to gene patents. Those who consider genes and other basic biological building blocks to be inherent products of nature also object to the current state of affairs. And lastly there are those that do not oppose patents on principle but object to the slacken application of the patentability requirements and claim that they have to be applied more stringently.

Today it is obviously possible to receive patent protection for basic biological building blocks and processes. To make a realistic analyze of whether genomic patents really do create problems and harm continuous progressive development or if they on the contrary promote scientific progress it is necessary to start off with an examination of the legal foundation. A description and analyze of the legal system will also help clarify the situation and make you understand why patents on genes and other basic biological products and processes originate such heated debates. I will thus proceed with an examination of the legal instruments in the current system and investigate whether they are adapted to their purpose and promote scientific progress and advancements or if they go beyond the law's initial intentions. Before we deal with present rules and regulations I will give you some background to the present-day situation.

[14] For example in Case 19/84, ECR 1985 page 228

[15] See for example: Case 15/74, Centrafarm v. Sterling, ECR 1974 page 1147. Case 187/80, Merck & Co v. Stephar BV, ECR 1981 page 2063

[16] Experimentundantaget – behövs en förändring?, Ann Sandmark page 14

5. The Legal Foundation

5.1 International Regulation

For a long time the idea of patents on biological organisms was unimaginable. But the revolutionary and rapid development of biotechnology has made them an every day event. In 1980 the very first gene patent was granted in the US and since then biotechnology patents are issued to an ever increasing extent. This development compelled the United Nations to initiate a convention aimed at preserving biological diversity[17]. The convention maintains that all genetic resources belong to all of mankind and should be collectively owned. The purposes of the convention are to preserve the biological diversity, to distribute the genetic resources justly and to ensure a durable use of the resources. But these objectives are obstructed by multiple international resolutions and agreements aimed at strengthening the legal right to biotech patents and to increase the scope of the granted protection. We are faced with mixed messages and I will give a brief overview of some of the international agreements regulating the patenting of genes.

5.1.1 General Agreement on Tariffs and Trade (GATT-Agreement), 1947

The primary aim of this agreement is to clear barriers to trade. But it also states a right to exclude certain areas from patentability. Inventions whose "exploitation would prejudice public order or morality, those involving diagnostic, therapeutic or surgical methods for the treatment of humans or animals, and inventions of plants and animals or essentially biological processes for their production"[18] can be excluded. When this agreement was entered into it was not possible to patent genes and the agreement does not mention genes for that obvious reason. But still it grants countries a right to self-determination regarding biotech patents among other things.

5.1.2 The Patent Cooperation Treaty (PCT) 1970 & the Patent Law Treaty (PLT) 2000

These treaties are administered by the WIPO (World Intellectual Property Organisation), which is one of the agencies of the United Nations and has 182 members. Numerous international agreements are administered by the WIPO who is, among other things, commissioned to promote the use and protection of intellectual property.

Two of the agreements are the PCT and the PLT. The PCT aims at facilitating applications for an "international patent". There is, as you probably know, no such thing as a proper international patent but this is as close as you can get. When an application is handed in to an authorized official authority or patent office a preparatory review of the application is made. Based on the results of the review the applicant can determine whether it is worth continuing the application process. If the results are positive the applicant can proceed by sending the application to all the different national patent authorities where the final review is made and patents issued. The object in view for the PLT is to support deregulations and a harmonisation of the legislation surrounding the application and maintenance procedures. To achieve this it states minimum requirements for patent applications and so on[19].

5.1.3 The European Patent Convention (EPC) 1972 & The European Patent Organisation (EPO) 1973

Contrary to common belief the EPO is not a part of the European Union, but is an independent legislative and executive body. All the members of the EU are contracting parties to the EPC

[17] Convention on Biological Diversity
[18] "NAFTA and GATT Intellectual Property Issues", Ladas & Parry LLP, Homepage
[19] WIPO Homepage

though and there are in total 28 member states[20]. The EPC was established to create a uniform European patent system and stipulates the overarching rules for the issuance of patents and the formalities surrounding the applications. It does not contain rules regarding patent infringement, invalidation or the detailed patentability requirements; this is left up to the national authorities to decide. This renders difficulties to arrive at harmonisation of the various national laws. The EPO also grants European patents for the contracting states through a centralised procedure. This allows an applicant to receive patents in all, or in a few, of the contracting states by a single application.

5.1.4 Convention on Biological Diversity, 5 June 1992

As I mentioned in the beginning of this section the purposes of this convention are to preserve the biological diversity, to distribute the genetic resources justly and to ensure a durable use of the resources. Art. 15 regulate access to genetic resources. All states are granted self-determination over their indigenous genetic resources and all access to them shall be "subject to national legislation"[21]. Other states are not allowed to exploit the genetic resources of another state without prior consent, and if permission is given the exploitation shall be conducted in collaboration with both parties if possible. This article has been introduced to prevent "bio-piracy" where industrialised countries "steal" the resources of underdeveloped countries and exploit them and the country of origin does not derive any advantages from the exploitation. Yet, states shall not prevent others from using their resources if the above mentioned criteria are fulfilled and the resources will be put to "environmentally sound uses"[22]. The agreement advocates that genetic resources should primarily be collectively owned as to achieve the above mentioned goals.

5.1.5 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 1994

TRIPS is a part of the multilateral agreement that establishes the World Trade Organisation (WTO), and was negotiated during the Uruguay Round (1986-94). It sets minimum standards for the protection of intellectual property in the WTO member states. The main content of TRIPS is trade-rules for intellectual property. The agreement also addresses *national-treatment*. This is a principle that establishes that countries must grant foreign residents the same or a superior level of protection for intellectual property rights as they grant their own nationals. A *most favoured-nation* clause is also included in the agreement. This clause denotes that any advantages granted to nationals of one country have to be extended to all other nationals too[23].

For the sake of this paper the most important portion is probably Article 27 which defines what inventions must be patentable and what is possible to exclude. According to the agreement patent protection must be available for virtually all technological inventions. All members must introduce laws that enable patenting and commercial exploitation of genetic resources. Thus the TRIPS agreement and the Convention on Biological Diversity are in opposition to one another.

In Article 27.3b, where biotech inventions are dealt with, it is settled that all microorganisms and non-biological or microbiological processes must be patentable in the contracting states. It is only possible to exclude patents on animals, plants, "essentially" biological processes for the production of plants and animals[24] and surgical, diagnostic, and therapeutic methods. Inventions

[20] http://www.european-patent-office.org
[21] http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-15
[22] Convention on Biological Diversity Article 15
[23] http://www.wto.org
[24] WTO, Homepage

can also be refused protection if their commercial exploitation would be against public order or morality.

5.2 Current Legislation

The patent systems in the US and in Europe are similar but not exactly alike. The United States have always been at the forefront of the development while the Europeans have been a bit slower. The Americans were the first to allow patents on genes and has vigorously encouraged continuous patenting of biological products and processes and Europe is following in their footsteps. I will now proceed with a closer examination of the American and European systems.

5.3 The path to biotech patents

It has always been much easier to patent basically everything in the US than it has been in Europe and biotech inventions are no exception. Recently there has been a trend towards stricter regulation, but the fact still holds true. Only "laws of nature, physical phenomena and abstract ideas" are exempted from patenting in the US[25]. The underlying reason for this is to secure access to technology and basic research tools[26]. Such being the case, it is not possible to patent abstract scientific and mathematical formulas and principles either, but even this standpoint is being challenged today.

Even in the US the attitude towards patents on "products of nature" was negative for a long time. The ruling on the patent application on pure tungsten[27] (1928) is illustrative of the former point of view[28]. Here the court granted patent protection for a method of purifying tungsten, but not for the tungsten itself. The court wrote that "Patents cannot issue for the discovery of the phenomena of nature… ….They are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none"[29].

But the US Supreme Court radically changed its position in the case Diamond vs. Chakrabaty (1980) where it established that it was possible to patent a certain oil-eating bacteria. The court did not think that there should be any "legally significant difference between active chemicals which are classified as 'dead' and organisms used for their chemical reactions which take place because they are 'alive'." The basis for their line of reasoning was that the bacteria were not solely man-made, it had been structurally modified and therefore it should be considered made by man. The microorganism should in other words no longer be considered as a natural compound since it had been converted into an "article of manufacture" and should be patentable on the same basis as other chemical products. An ordinary chemical is patentable if it is modified in some way, e.g. structurally modified, purified or if something is added to it[30]. Even the inventor Tom Chakrabarty was surprised by the decision of the court. He stated that all he had

[25] Protecting and Transferring Biotech Inventions, H.H. Lidgard et al, page 30-31
[26] Intellectual Property Rights in Biotechnology, Arti K. Rai page 2

[27] Tungsten is the metal that has the highest melting point and lowest vapour pressure of all, and at temperatures over 1650°C has the highest tensile strength. Tungsten is used in electrical contact points for car distributors, X-ray targets, windings and heating elements, missile and high-temperature applications, TV-tubes, paint et cetera.

[28] Patented Genes: An Ethical Appraisal, M. Sagoff page 2
[29] Patented Genes: An Ethical Appraisal, M. Sagoff page 2
[30] Intellectual Property Rights and the Life Science Industries. A twentieth Century History, G. Dutfield page 154-155

done was to use a common method to exchange genetic material between bacteria and that this process also occurs spontaneously in nature[31].

The next step in the development was the case concerning an application for a patent on "polyploid oysters" (1987). The court refused the patent itself but in the verdict they spoke in favour of patents on multicellular living organisms. Thus they made it possible to patent higher life forms and it is still possible today[32]. The following year the onco-mouse patent was granted, the first ever patent for an animal.

5.4 The 1980 Bayh-Dole Act

The Bayh-Dole Act was introduced to grant universities and other public institutions full privilege to all of their inventions and a right to protect them as they see fit. The institutions themselves are also entitled to all returns and other advantages derived from the patented inventions. In exchange for this the government retains a so called "march in right", in case they consider inventions underdeveloped or underused. They also require research results to be published after a certain period of time. The government can also patent the inventions that the universities and researchers have passed on[33]. If and when inventions are protected and subsequently commercialised, there are usually agreements granting the universities the major part of the rights and revenues and the researchers only receive a smaller percentage.

Since the introduction of the Bayh-Dole Act the pattern of behaviour of researchers, universities and other public institutions has changed quite a lot. Previously open access to research results was the norm but nowadays they all do their best to protect and commercialise their results, either independently or through collaborations with private corporations. The Act was incorporated into American legislation to achieve precisely this effect. It has been proven that it has had a positive effect on the technological innovation[34] and today more research results are being commercially exploited. Despite these positive results the Bayh-Dole Act is not only beneficiary for the innovation process but also give rise to serious problems. The open-access policy has been replaced with a limitation of the access to scientific data, early stage inventions and research tools. Licences are frequently used but they are often exclusive and licensing fees are many times high. This state of affairs creates barriers to access for both private and public entities and will adversely affect the costs and efficiency of research.

More and more upstream inventions are also being patented. This is a logical consequence seeing that universities and other public institutions are very active in early stage research and do not produce marketable products to any large extent. When these fundamental sources of information are being patented access will be seriously restricted and the incentives for innovation will be diluted. The fact that most of the academic institutions also lack the administrative skills necessary for an effective distribution and utilization of the patents is another aggravating factor.

A prospective positive result created by the act is that the universities in America and Europe have become more business oriented and they monitor their results more closely. In the long-run

[31] Patented Genes: An Ethical Appraisal, M. Sagoff page 3
[32] Intellectual Property Rights and the Life Science Industries. A twentieth Century History, G. Dutfield page 156-157
[33] Protecting and Transferring Biotech Inventions, H.H. Lidgard et al. page 64-65
[34] A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property environment, by J. H. Reichman and Paul F Uhlir, page 12-13 and 26.

that can make them more independent of public funding. But the increased collaborations with the market have large disadvantages as well. There is a great risk that "small areas" and the diseases of the poor are being neglected since these are not very profitable projects. There is also the fact that most of the revolutionary discoveries are made when researchers are working on unprejudiced tasks. The academic institutions new way of dealing with their results obviously raise many questions and because of this I will examine the issue in more detail below.

5.5 Biotechnology Patent Act

Another important development was the introduction of the **Biotechnology Patent Act** (1993). It was incorporated into American legislation to protect domestic companies from foreign competition. The object in view was to prevent imports of products that were being manufactured in other countries with the use of known processes. Since the processes were known they were not patentable subject matter in the US. For the biotechnological industry this was problematic. It was possible to patent a microorganism, but it was not always possible to patent the product resulting from it or the procedure that the product was made by. It is often the product that is valuable for companies and not the microorganism in itself. An example could be if you had patented the DNA sequence that code for insulin. You would then not be able to patent a known process for manufacturing the insulin and not the insulin either since it is a known substance. Because of this it was possible to produce the known substance (insulin) by using the known process and export it to the US. To counteract this, the Biotechnology Patent Act was consequently introduced. The new act abandons the customary criteria and states:
"Notwithstanding any other provision of this section, a claimed process of making or using a medicine, manufacture, or composition of matter is *not obvious*[35] under this section if...
(1) the machine, manufacture, or composition of matter is novel…..and non-obvious
(2) the claimed process is a biotechnological process……"[36]
This resulted in a situation where known processes that are used to produce something new are all of a sudden considered patentable and the imports are possible to prevent.

5.6 Directive 98/44/EC on the Legal Protection of Biotechnological Inventions

In 1998 the EC adopted the Biotech directive[37] which is influenced by the TRIPS Agreements and the EPC amongst other things. The Directive creates homogeneous boundaries for what shall be patentable within biotechnology in Europe[38] and establishes procedural regulations.
The Directive was introduced because the existing regulations were not satisfactory or uniform and there was also the intention to promote investment in the biotech industry. As said, Europeans have traditionally been more sceptical towards patenting of biotechnology than the Americans, and a protracted debate preceded the acceptance of the directive. The directive should have been incorporated into national legislation before the end of 2001 but some countries have still to fulfil that duty. The directive is incorporated into Swedish law as of May 1st 2004[39].

The heart of the directive is found in Articles 3(2) and 5(2). Here it is stated that "biological material which is isolated from its natural environment or produced by means of a technical

[35] My italics
[36] Intellectual Property Rights and the Life Science Industries. A Twentieth Century History, G. Dutfield page 158
[37] Om biotekniska uppfinningar 98/44/EC
[38] European Parliament and Council Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions, OJ 1998 L 213/13
[39] Prop. 2003/04:55 Gränser för genpatent m.m. – genomförande av EG-direktivet om rättsligt skydd för biotekniska uppfinningar

process may be the subject of an invention even if it previously occurred in nature" and that "an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element".
These provisions confirm what had previously been established through EPO case-law. As early as 1995 it was determined that DNA should not be considered a naturally occurring phenomenon. When isolated it shall instead be considered a chemical substance which carries genetic information.

Beyond this the directive states that one cannot patent components of the human body that are merely discovered[40]. On the other hand isolated, purified, duplicated or artificially made components can. The fact that a component is identical to the naturally occurring structure is not an obstacle. It is the isolation and duplication that is key to the opportunity to patent naturally occurring phenomena. The explanation given is that in nature DNA-molecules do not occur isolated, instead they are attached to other genes forming a chromosome. Because DNA-molecules cannot isolate themselves it is not considered to be a mere discovery. The separation requires human intervention and thus patents supposedly do not cover anything that occurs naturally, and the DNA is "transformed" into a chemical as the result of these technical processes[41].

5.6.1 The Patentability Requirements

Generally speaking products consisting of biological material are patentable if they fulfil the patentability requirements. There are three patentability requirements; in Europe they are Novelty, Inventive step and Industrial application, and in the US Novelty, Non-obviousness and Utility[42]. The requirements place very similar demands on inventions and to simplify the presentation I will discuss them together. The requirements for biotech inventions are identical to the general patentability criteria, but how gene-sequences, proteins et cetera fit into these criteria is still to some extent unresolved.

5.6.1.1 Novelty

The novelty requirement is fulfilled by the isolation and a description of a sequence. It is not necessary to be able to describe all properties of a gene-sequence, basically it is considered novel if it has not been described before.

5.6.1.2 Inventive step/Non-obviousness

The inventive step requirement is quite easily fulfilled. In the early biotech research work it took ingenuity and regenerative work to isolate, describe and to work out the function of genes but today it is simple routine work and it can even be performed by mechanical equipment. There are moreover extensive databases that aid in the identification of gene-sequences. Regardless of these facts the mere isolation and description of a gene is still considered to fulfil the inventive step requirement.

Through American case-law it is possible to draw the conclusion that there are basically no limitations to the patenting of DNA on accord of the non-obviousness criteria. Traditionally the non-obviousness criteria require that an invention cannot be obvious to a person skilled in the art

[40] Article 5, item 1
[41] The Swedish patent agency, PRV. Homepage
[42] Protecting and transferring Biotech Inventions, Lidgard et al. Page 20-21 and Article 3(1) Biotech Directive

at the time of the invention if it is to be patentable. But, according to case-law it is possible to patent a gene sequence as long as no one has patented that particular sequence previously. This holds true irrespective of the fact that the sequence might be identified with the use of a known process for isolating genes[43], the generated results are still not considered obvious. More precisely, the method used is trivial and the only legally relevant question is whether the sequence is identical to any other patented sequence or not. When considering what a person skilled in the art knows today it is doubtful whether the isolation ought to be considered inventive anymore.

Lately the EPO has taken a slightly stricter position and established that DNA-sequences that are structurally very similar to another sequence which has a known function shall no longer be patentable[44]. But the USPTO have on the other hand kept their original position. In the US the decisions are thus based solely on whether a sequence is obvious before the isolation or not. Since it is very hard to predict a sequence before it is isolated, even sequences identified by machines will be considered to have inventive step[45].

5.6.1.3 Industrial application/Utility

Lastly it is necessary to demonstrate that the invention has utility/industrial application. Previously the industrial application requirement was narrower than the utility requirement, but USPTO has issued stricter guidelines which require the applicant to present "credible, specific and substantial utility"[46] to qualify for a patent and this has brought the two requirements closer together. Today the criteria hence place very similar demands and I will therefore refer to them both as utility.

The question of utility is taken up on a case to case basis. It is sufficient to specify one commercial application for a sequence and if the gene sequence has a known therapeutic or diagnostic effect it is obviously patentable[47]. But most of the time DNA sequences, proteins etc have not been used for anything yet, so how can it then have utility? The fact is that it is sufficient to e.g. show that a gene-sequence code for a protein and that that specific protein in turn has a known function or some experimentally derived properties. An alternative is to use the sequence as a probe, research tool or something of the sort. It is even possible to merely state a theoretically possible function for the sequence to be granted patent protection[48]. Considering that a granted patent will cover all future and present uses of a particular sequence it is hard to understand why the utility requirement is not more strictly applied.

It must be counter productive to grant protection for basic research results on such weak grounds. DNA sequences are extremely important for future research and innovation, and should as such not be handed over to companies without there being some true innovations made. Patent protection is traditionally motivated and justified by the speeding up of technological advances and as a reward for efforts made. Is it then wise to grant protection for work that hardly demands any intellectual or creative contributions? I believe that patent law would serve the interests of the public better if this information would be freely available and could be used in multiple research projects free of charge.

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[43] Intellectual Property Rights in Biotechnology, Arti K. Rai page 4
[44] The Ethics of Patenting DNA, Nuffield Council on Bioethics, page 30
[45] The Ethics of Patenting DNA, Nuffield Council on Bioethics, page 30
[46] Revised Interim Utility Guideline Training Materials, USPTO Homepage
[47] Experimentundantaget – behövs en förändring?, Ann Sandmark page 22-23
[48] The Ethics of Patenting DNA, Nuffield Council on Bioethics, page 31

5.6.2 Written Description

The patent applications must include a written description of every claim included and this put some restriction on the patenting of DNA though. The written documents have to be precise enough to prove that they have the invention in their "possession". For instance you have to describe in sufficient detail how to clone a gene, the appearance of the sequence and how to clone variants or homologs of it. Thus it works almost like an enablement requirement because it is not sufficient to merely describe the method. You have be able to actually perform the method and show the results, in other words isolate and sequence, and this limits the possible scope of the patents to some extent[49].

5.6.3 Unpatentable inventions

According to Art 6 of the Biotech Directive it is not permitted to patent inventions made for cloning, germ-line modifications, for embryo processes or to modify the genetic identity of animals if the modifications are likely to cause them suffering. Thus it is not possible to patent methods for changing the genes in human sexcells or for the reproductive cloning of humans. The ground for this is that it is considered to be contrary to *ordre publique*. According to EPC it is not allowed to patent treatment methods for humans or animals[50]. Thus surgery, diagnostic and therapy methods are not patentable either. But new substances or compositions can be patented on the other hand, as well as their use in any of these treatment and/or diagnostic methods.

In the US inventions such as treatment and diagnostic methods and discoveries are all possible to patent. Methods for medical treatment are patentable irrespective of whether the method involves surgery, a medical device or the administration of a drug.

5.7 Available types of patents

There are three kinds of patents available for biotechnology and pharmaceutical inventions[51]. When a chemical substance is patented expressed as a chemical formula with a closer description of its characteristics, e.g. a DNA sequence, it can be protected by a so called ***product-patent***. It covers the invention itself as well as all present and future uses of it. Even unknown future uses are included in the protection. To be granted a product-patent it is sufficient to describe one commercial application for it. Irrespective of the fact that all properties of the substance are described or if they are not, they are all included in the patent and this originates an unlimited product protection.

The second kind is the ***process-patent*** which is received for new methods to manufacture and produce chemical substance, e.g. a protein that a DNA sequence code for. The substance itself does not have to be new.

The third and last possible patent is the ***use-patent*** which is granted for the use of a "new" chemical substance in any given field or for a known substance in a new field of application. It is necessary to specify the particular purpose for the technology if the application shall be granted[52].

It is Art 9 of the Biotech directive that makes it possible to receive product patents on genes. The opportunity was possibly introduced to avoid a situation where many different patents would be

[49] Intellectual Property Rights in Biotechnology, Arti K. Rai page 4-5
[50] http://www.european-patent-office.org
[51] Experimentundantaget – behövs en förändring?, Ann Sandmark page 22-23
[52] The Ethics of Patenting DNA, Nuffield Council on Bioethics, page24

granted on variations of the same sequences. But product patents create problems since they not only originate an unlimited protection for all current uses but for all future uses as well. The owner is granted a protection unjustly wide in its scope. They create other problems as well. Product patents protect inventions that are defined as the results that they achieve, in other words, they solve technical problems. The problem can for example be the identification of a mutation in a gene. The patent-holder is granted a patent that includes all possible technical solutions that produce these results. In this case all the technical solutions to finding a mutated gene. The problem with this is obviously that it is not possible to anticipate all possible future technical solutions to any particular problem. Since additional R&D is deterred, more effective solutions might never be identified bringing higher social costs in its train. The original patent owner is thus granted a sensationally wide protection.

5.8 Problems brought forward

Since the 1980 decision of the U.S. Supreme court patents have been used to protect genes, proteins, cell-lines and other biological products and processes to an ever increasing extent. But the application of patent law to genomic inventions has been questioned and the American guidelines and the Biotech directive widely criticised. The main points brought forward are the lack of distinction between inventions and discoveries and the extremely broad patents that are being issued. The questions brought forward concern both the application of the law as well as policy issues such as access, cost and efficiency of research. These issued are interlaced and I hope that my presentation has made this obvious.

The underlying problem is the properties of the genomic patents themselves. All patents limit access to the patented product but regular patents can be further developed and built on even though the invention itself cannot be used. But when a gene sequence is patented it is the information itself that is protected and this has the effect that even though the information in the patent is disclosed no-one is allowed to use the information to develop it further since the information itself is the invention. This subsequently has the effect that the early discoverers get total control over all downstream development. When patents are not limited to a specific use or have overly broad scopes these problems are aggravated. This state of affairs does not promote the progress of science. Thus the patentability requirements must be applied more strictly than they are today and it is probably safe to say that if product patents are to be granted in this field they should at least be limited to a specific use.

5.9 Patent appeals

Since 1982 the US Court of Appeals for the Federal Circuit (CAFC) handles all patent appeals from the different US District Courts. The CAFC was introduced after strong pressure from the market for the arrangement of such a court. The market has always propagated for stronger protection of biotechnological inventions, and the American government seem to have been listening. The purpose of the court is to ensure uniformity in the application of patent law. The CAFC decisions can be appealed to the Supreme Court but that rarely comes about. Accordingly, the great majority of patent law is determined by the CAFC case-law. In my view it is a splendid idea to have a court like this. If all expertise and knowledge is kept in one place there is a greater chance of creating a concise application of patent law.

Unfortunately the CAFC has been criticised for their slacken application of the patentability requirements for biotech inventions and it has a tendency to strengthen and preserve most patents

appealed[53]. It appears that it is quite easy to qualify for patent protection. Particularly the non-obviousness requisite and the written description criteria have been "adapted" to facilitate the patenting of biotechnology[54]. The standpoint taken by the CAFC reinforces the negative consequences that the rules and regulations give rise to and make it hard to invalidate objectionable patents.

5.10 ESTs

Today it is less and less time-consuming to identify and describe genes. This is due to the so called "Expressed Sequence Tags" (ESTs)[55]. ESTs are machine-made shortcuts to finding genes and are really just a copy of a small part of a DNA-sequence. It is used to identify unknown genes and to locate their position in a genome.

When the first application for a patent on ESTs was deposited in 1993, the USPTO rejected it on the ground that none of the requisites could be fulfilled [56]. In 1997 they had a new hearing on the subject and this time the USPTO decided that they would grant patents on ESTs if and when the requisites were fulfilled. That would be accomplished if the ESTs were used as a tool to locate a full length gene or to improve the understanding of the evolution. Nowadays it is possible to patent ESTs and gene fragments. They can even be patented before there is a known use for them and before it is possible to determine the corresponding gene, function or protein. For me it is quite hard to grasp how the utility and enablement requirements are fulfilled in these circumstances. Even if there are no legal reasons not to grant patents on ESTs they are opposite the original purpose of patent law and I cannot see how they could economically spur research either.

As opposed to European practice where only single ESTs can be patented it is possible to patent up to ten ESTs in each patent application in the US. This possibility has been extensively used. One company, Incyte Pharmaceuticals Inc., have for example applied for patents on 1,2 million gene fragments and Hyseq Inc. for 900 000 gene discoveries[57]. There have not been any applications for patents on ESTs made to the EPO which is probably due to the fact that you have to pay one fee for every EST which makes protection very expensive.

The risk of overlapping patents increase greatly when ESTs are being patented. One gene can be covered by patents for many different ESTs as well as for the whole sequence or the gene can be included in a patent on another region that also controls that particular gene[58]. In the US it is also possible to patent an entire gene, in which a large number of previously patented ESTs can be included. These patents will probably obstruct and further raise the price for research.

5.11 Algorithms

If we are to foretell the future, the following trend in the development will probably be the opportunity to patent algorithms. The US Supreme Court has already pronounced that "even though a mathematical algorithm is not patentable in isolation, a process that applies an equation to a new and useful end is at the very least not barred at the threshold"[59]. In light of this

[53] Intellectual Property Rights and the Life Science industries. A Twentieth Century History. G. Dutfield page157
[54] Intellectual Property Rights in Biotechnology, Arti K. Rai page 4
[55] ESTs Fact sheet, NCBI's Homepage
[56] The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs, L.B. Andrews page 8-9
[57] The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs, L.B. Andrews page 9
[58] The Ethics of Patenting DNA, Nuffield Council on Bioethics, page 31
[59] Biotech Patent Fights, J Van Brunt page 6

statement patenting of abstract ideas and algorithms are very likely to come about. If it does it will heavily impact the biotech industry that is highly dependent on computing. Most experiments are not carried out in reality, it is computed instead. If these methods will be patentable in the future, there will be more obstacles for researchers to overcome. It is already hard to afford licensing fees and to be granted licences on necessary research tools et.c. It is easy to see how this development would create even greater problems and increased costs. Exactly how it will be possible to draw the line between a mere discovery of a scientific principle and the invention of one is not for me to say, but it sure does seem difficult.

5.12 Teknonationalism

Not too long ago the main objective of the researchers was to publish their results and share them with the world, thereby receiving due credit and recognition. The results from this mostly basic research were added to the collective "knowledge bank", the so called research commons. Today the situation is quite different. The sharing and cooperation ethos are beginning to disappear. Many results are kept secret, as not to ruin the novelty criteria and negative and unsupportive results are hidden in a drawer somewhere. When scientific articles are published they often merely contain limited presentations and nowadays secrecy-agreements prevent many researchers from mentioning anything whatsoever regarding their projects. This transfer towards proprietary research will most certainly lead to duplicate efforts and the technological innovation will be slowed down.

The basic research made within the biotechnology sphere is part of the so called “small-science environment”[60]. Here the researchers cannot find that much data that is useful for them in the large databases. Instead they create small networks where the researchers communicate with each other and make informal exchanges of data. The specific results from one researcher can give rise to, and serve as a basis for, new studies which in turn is further built upon and so on. The result from this basic research in biotechnology often demonstrates how natural objects and processes are characterised. If the basics and the supporting documentation are not widely available the work of the researchers will be obstructed or delayed on account of the limited amount of data that is obtainable.

Additionally much of the basic research has been, and still is, publicly funded. It only seems fair that results from these research projects should be made publicly available. Instead the previously public information is being protected. Taxpayers financed the research in the first place and should not have to pay for these advances twice, but this is hardly the case today. The researchers, and the companies that commercialise their inventions, are the ones that get the returns. We cannot be sure what the long-term effects will be but we are without a doubt in a very precarious situation. I believe that this problem has to be addressed in global analyses and that appropriate measures should be taken.

J. H. Reichman and Paul F Uhlir have drawn a comparison between this situation and the situation with ordinary public-good’s that I think is to the point[61]. The government finance roads, street lighting et cetera at zero marginal cost and as a resulting effect private entities make downstream products that build upon these things. The basic research being conducted within biotechnology could be placed on equal footing with the other public-goods. The basic research is not profitable enough for private companies to carry out in most cases, and because of this the

[60] A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property environment, by J. H. Reichman and Paul F Uhlir, page 13-15

[61] A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property environment, by J. H. Reichman and Paul F Uhlir , page 23

state finances it. The commercial entities should have free access to the results to be able to develop applications that build upon these results. We need to call in question whether it should be possible for companies to take control over the public goods/research results as is the case today. Should they not remain available for everyone to use?

5.13 The Universities inventions

There is no uniform regulation in Europe regarding title to the inventions made at universities and the matter is handled in various ways. In the UK there is no regulation at all and the universities are free to handle the matter as they please. In Sweden, Finland, Germany and Denmark there are exemption rules regarding "employee-inventions" for university employees. In Sweden we have the so called "Teacher's exemption-rule"[62]. The principal rule in Swedish legislation is that a patentable invention made by an employee is transferred to the employer. But it exempts "teachers at universities and institutions for higher education"[63] from the legislation. This results in them having right to all of their patentable inventions, even those made in line of their work. A distinguishing quality is the fact that the rule only applies to teachers and not to researchers. But this fact might not make a huge difference since most of the researchers have an appointment which requires teaching. It is possible to depart from this legislation in individual employment agreements.

In the US researchers own their own inventions, that is to say, if there is no agreement determining otherwise or if the researcher is employed for the sole purpose of carrying out research[64]. Usually there are agreements between the universities and the employees as to the division of rights. The privileges granted to the universities are regulated by the Bayh-Dole Act.

Post the Bayh-Dole Act universities and other public institutions have started to exploit their results extensively. Between 1993 and 2000 US universities alone were granted approximately 20 000 patents. Some of them have generated millions of dollars in revenues while some remain unexploited. The American universities have by far generated the largest amounts of income and have received over USD 1.2 billon from licensing and are followed by Germany which has generated EURO 46.5 million[65]. Commercial companies sponsor much of the research conducted at the universities. They expect specified results in return for their investments and because of this it has been called into question if there is enough independent academic work done today. Independent work is important since numerous innovations derive their origin from research where no specific results are sought after. Seeing that the sponsors have a specific task that they want the researchers to focus on it can be established that the universities approach is narrowed down and important future discoveries jeopardized. This trend will also have negative social effects because less original and pioneering work that can serve as the basis for future innovations will be generated.

Increased exploitation and commercialisation of research results is useful and important for the growth of the economy but not all exploitation is in the best interest of the public. The individual researchers are able to withhold important data for private gain. The researchers can make substantial amounts of money if their inventions or results are protected and then sold or licensed to a high price. This opportunity is obviously appealing to the individual researchers who might be reluctant to share their results with others as not to ruin the novelty criteria or expose

[62] §1 Lagen om rätten till arbetstagares uppfinningar (1949:345)
[63] Free translation
[64] Protecting and Transferring Biotech Inventions, H.H. Lidgard et al, page 61
[65] Turning Science into Business, Patenting and Licensing at Public Research Organisations, OECD Report

important findings to others. If this scenario takes place the amount of available scientific data will be further restricted and the public will have to pay for research they have already financed. In the opposite situation, i.e. when researchers are under no obligation to report their findings, is just as bad. If the findings are never reported they cannot be further developed into marketable products. But even if the results are identified the majority of the universities do not have sufficient means to exploit the results fully and they are not always best suited to exploit and commercialise the results. This has caused them to licence the technology and knowledge out instead. Thus the knowledge generated at universities end up on the commercial market and is further developed there precisely as they were previously, with the one important difference that the knowledge does not come for free anymore. The increased costs will undoubtedly be carried by the consumers in the end. The revenues are obviously valuable for the universities, or the researcher, but increased protection for their knowledge and discoveries reduces the amount of available data even further and it is doubtful whether it is this role the universities should have.

Following the current trends it thus becomes apparent that there will be a shortage of available information and data in the future. When access will become dependent on settlements between private entities and the academic institutions it will inevitably lead to higher transaction costs, lock-out effects et.c. I will finish this section with the observation that we need to review what kind of system that will be the most appropriate in the long run. The universities have become too market oriented and the interests of the public are ignored.

6. Further aspects of the patent requisites

One of the cornerstones in patent law has always been that pure discoveries are unpatentable. But case-law and international doctrine has changed this fundamental rule and nowadays there are large opportunities to patent naturally occurring phenomena. The DNA-sequences have been turned into a chemical in the eyes of the law and ordinary patent principles have thus been possible to set aside. Genes are undoubtedly plenty useful in diagnostic- and treatment methods among other things, but is it advisable to allow patenting to the extent that we do today? Biotech patents have up until now been granted extremely wide scopes, which inevitably will lead to delays and blocking of improvements and new innovations. Is this really an appropriate and necessary line of action considering the problems and dangers this creates for future scientific progress? And should genes continue to be eligible for patenting or would it be more appropriate to regard them as public assets? There is no obvious answer to these questions but I will in the following analyze and discuss the issue even further.

6.1 Is the material novel?

One of the classical pro-patent arguments is that proteins, DNA sequences et cetera do not exist in nature in its purest form and therefore they must be regarded as novel patentable subject matter[66]. This argument has really hit home but it is actually quite easy to dismiss it. Irrespective of the fact that isolated genes and proteins do not occur isolated they still possess the same qualities as in nature. These properties did not arise due to any inventive work on the researcher's behalf, they are simply the natural properties of the biological material and when isolated they accordingly retain the same functions and properties. No inventive activities are required and no new utilities or properties are created, the sole inventive activity is the isolation. Without these natural properties the industry would not have any use for them in the first place. Exactly how the biological material becomes novel by simply isolating it from a body or a plant is unclear to me. Current technology easily handles the isolation and identification of various genes and it can even be done by machinery. Consequently it is mere routine work and does not motivate protection. In addition genes are no ordinary chemical substances. The DNA is in essence encoded information that governs several hundred thousand proteins. It is this fact that distinguishes genes and it is a misjudgement to draw a parallel to other chemical substances.

6.2 Is there any inventive step?

The central question in connection to the review of the inventive step/non-obviousness requirement is as I said before whether the invention would be obvious to a person skilled in the art or not. In essence it is determined by how much creativity and inventive work that has been laid down. According to EPO an invention is obvious if it "does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art, i.e. something which does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art"[67]. Based on this definition results generated by automated sequencing machines and databases must be considered obvious. To my knowledge there has not been any passable arguments explaining how the mechanically generated information can possibly fulfil the inventive step criteria, and the information must thus be considered to be discovered. Still, there is real inventive work being done and these inventions should naturally be patentable. But the criteria needs to be applied much stricter than it currently is.

[66] Patented genes: An Ethical Appraisal, M. Sagoff page 1-3
[67] Guidelines for examination, Chapter IV Patentability, EPO Homepage

To develop and introduce pharmaceuticals or other applications to the market is a time-consuming and costly process. The research and development and the clinical trials for safety and efficiency are costly and might not always end up in an approved new drug. Hence it is a risky business, but the payoffs are potentially extremely large. The pharmaceutical companies get a strong protection against generic drug manufacturers and extended patent protection in return for their efforts. On average it takes 9-11 years to get a drug to the market and the maximum time for the extension is five years both in Europe and in the US, but in Europe there is a limit of fifteen years of actual protection[68].

The extended protection has been awarded because of the high risks and costs associated with drug development. The industry and the legislators claim that research would not be performed if it was not possible to patent the results of their efforts. Obviously this holds true for most inventions but considering the small efforts needed to isolate e.g. gene sequence and ESTs this argument does not hold in these situations. In my opinion identification and isolation would be done even if protection was not available because of the small efforts needed. It is the applications that are expensive and time-consuming to develop and that demand great inventive and creative efforts and these are possible to protect as just mentioned. Thus this is yet another argument for a stricter application of the requisites.

6.3 The Utility requirement

The utility requirement is currently very easy to fulfil as well. As I mentioned above it is enough to specify one plausible application for a gene to claim monopoly rights to all anticipated and unanticipated uses of that gene[69]. To be granted such a wide protection is on all occasions unfortunate and improper. It overcompensate the patent holder and leads to serious blocking problems. When the patent owner do not know the function of the biological substance or what uses it has the situation is obviously even worse. These patents give rise to numerous unsatisfactory incidents.

Such an incident arose due to the patent on the CCR5 receptor. In February 2000 Human Genome Sciences Inc. (HGS) was granted a patent for the CCR5 receptor. The application was filed in 1995 and in the patent claims HGS stated that the primary area of use for the receptor would be as a cell-surface receptor to be used in development of anti-inflammatory treatments. At the time they were not quite sure what the applications for the protein would be, they only made speculations as to its role in a range of diseases, e.g. cancer, arthritis and allergies.

Six months later other researchers discovered that the CCR5 receptor is the transmitter that brings the HIV virus into human cells. It was proven that the protein is the carrier that brings the virus into the host cells and this result in the receiver being infected. It was also discovered that some people do not have any CCR5 receptors which makes them immune to HIV and that is what makes the receptor so interesting[70]. Since HGS has a product patent on the CCR5 receptor this and all other functions are included in the patent, despite the fact that HGS was unaware of this function when they submitted their application.

This highlights the problem with very wide patents. It is questionable whether later identified functions should be included in the original patent this way. Fortunately HGS has been very generous with licences, but the question remains; what effect will these broad patents have on future development and the public good? My opinion is that we ought to require that applicants

[68] Protecting and Transferring Biotech Inventions, H.H. Lidgard page 141-146
[69] The Ethics of Patenting DNA, Nuffield Council on Bioethics page 41
[70] The Ethics of Patenting DNA, Nuffield Council on Bioethics page 41

define what the specific utility for their invention is and limit the protection to that application. If that was the case situations like this would not arise and future development would not be obstructed.

Lastly, wherein lies the benefits of granting protection for inventions that have no apparent or known use yet? They make no inventive contributions and should therefore not be considered to be inventions. It is not reasonable to grant protection for something that is only possible to do in theory. To assume that a gene will be of use in gene therapy is a common prediction that is sufficient to motivate patent protection today [71]. But since all genes are theoretically possible to use in gene-therapy it does not take a genius to figure that out. When patents are granted on such loose grounds they will only prevent further research and development, not bring it forward.

6.4 Blocking patents

The existence of blocking patents is not unique for the biotech industry. Intellectual property is, as you probably know, not only a tool to protect technology, it is also a strategic weapon that companies use to block and outmanoeuvre their competitors and to prevent other actors from developing competing technologies et cetera. It's a natural component in all market economies. But blocking patents affect the biotech business much harder than in other fields. There are many reasons for this fact.

First of all it is rarely possible to invent around patents on genes. This is primarily because the information contained in the genes is what is being patented, as previously discussed. But it is also because the number of genes is finite. Once the genes have been analyzed and patented, the blockade effect is hence much more extensive than in other areas where unlimited variations and experimental modifications can be made. Thus gene patents retard the development of competing and complimentary products to a larger degree than patents in other sectors.

An additional problem with wide and numerous patents is that the number of research paths most likely will be reduced, and in some cases innovation can be totally blocked. Particularly patents that are granted early in the research process have this effect and thus conflicts the original purpose of patent law. These patents also cause unjustified and unnecessary costs for downstream developers. When companies are interested in developing a technology it is a costly and lengthy business to identify all the relevant patents and possible patents pending. Negotiations on licences do not always run smoothly either. If an agreement cannot be concluded with one of the parties concerned, the whole project will fall. But even if an agreement is reached the costs will be increased since the developers need to pay royalties to all the licensors. This will result in severe costs for research that there is no guaranteed payoff for.

There will be problems for the second generation inventions as well. Because the improvements incorporate the first patent it is necessary to receive a licence to practice the second generation invention. The owner is put in a superior position and can e.g. demand a large share of the revenues from the improvement and the improver might not receive a sufficiently large share as a resulting effect. In addition, many of the initial right-owners are probably not that keen on competing with a lot of improvements, and will avoid this by practicing restrictive licensing practices or not license at all[72]. Inventions that do not necessarily compete with the original patent can also be prevented from being made. If the owner applies this strategy we will have a situation where only a single developer is working on a new technology.

[71] The Ethics of Patenting DNA, Nuffield Council on Bioethics page 61
[72] Genetic Patents: Gatekeepers to the promised cures, L. P. Westin page 4

Complications also arise because we still do not know exactly *how* genes function. It has not been possible to define DNA with sufficient precision since the sequences recombine in new ways and interact in a complex manner with other sequences or the environment. How the genes code for protein is not clear either. There is some initial knowledge of the processes but it appears to be impossible to transform the knowledge into a precisely defined patentable object. This means that what is being patented today is basically just intellectual constructs. The more we learn about how genes produce protein the more complex the process turns out to be. Currently we have learned that often more than one gene is involved in the creation of a particular protein. In some cases it is necessary for different processes to occur simultaneously, and these processes are in turn controlled by other proteins which are created by other genes[73]. Each gene does not work in an isolated vacuum, they are in a state of dependence and cannot be seen as individual entities. As our knowledge of these intricate relationships of dependence increase more and more patents will be found to be blocking one another and the situation will be further complicated.

[73] Intellectual Property Rights and the Life Science Industries. A Twentieth Century History, G. Dutfield page 163-164

7. The various kinds of biotechnological inventions

The debate on the patentability of biotech risk being to general when the different groups of inventions are lumped together and discussed jointly. Patent protection might be motivated in one or more of these groups but not in other and therefore it is more to the point to divide the topic into smaller sub-groups. It is possible to distinguish four different groups and I will proceed by taking a closer and more detailed look at these.

7.1 Diagnostic-tools

It can be ascertained that patents on diagnostic tools grant protection for the association between a gene and a disease. Tests are designed to identify mutations by making a comparison between the appearances of a patient's gene sequence with that of a normal sequence. The ability to identify a mutation in a gene is sufficient to fulfil the utility requirement and receive patent protection. It is not necessary to be able to account for what effects the mutation will result in, i.e. which disease it causes. It is furthermore not necessary for tests to be capable of identifying all possible mutations that can cause a disease[74].

Patents on diagnostic tools often have a very wide scope. In most cases the patents include the mutated as well as the normal DNA sequence and the protein that the sequence code for. The resulting effect is an exclusive right to screen for a particular mutation no matter how the screening is done. The patent not only covers the patented tool but all future screening that could identify the mutation as well. Since the proteins are included in the patents it is not possible to develop alternative tests that screen for these specific proteins without a licence. All future research and development of diagnostic tools will thus be dependent on the original patent.

If the patent owners were in the habit of making licences widely available there would be no problem, but this is not necessarily the case. The most famous example of how companies can misuse their monopoly position this way is probably the case of Myriad Genetics and "their" genes BRCA1 and BRCA2. The story illuminates the problems associated with very broad patents on diagnostic tools. In most literature it is presumed that licence-agreements will be readily made and everyone will live happily ever after, but apparently this is not the case. The story also highlights the fact that all companies do not act the way the economists and other great thinkers ponder that they will act. But let's get back to that and I will start by telling you the story.

7.1.1 Myriad Genetics

Back in 1994 Dr Mark Skolnick and the American company Myriad Genetics (MG) took up the results that a geneticist named Mary Claire King had brought forward. She had been able to locate the gene BRCA1 which is responsible for hereditary ovarian and breast cancer. She had not been able to prove the function of the gene, but Dr Skolnick and MG used her results and were later able to do that. They were also able to prove the function of another gene, BRCA2, which influence the heredity of these diseases as well.

Myriad Genetics sought and was granted patent protection in the US, Australia, New Zealand and Europe. MG received product patents on the BRCA1 and BRCA2 genes, thus the regular sequence as well as all mutations are included. In addition they have patents on the proteins that the genes code for and use-patents for the use of the sequences in diagnostic work[75]. MG has not

[74] The Ethics of Patenting DNA, Nuffield Council on Bioethics page 48-52
[75] The Ethics of Patenting DNA, Nuffield Council on Bioethics page 48

only patented the genes but has also received a range of complimentary patents ranging from diagnostic tools to therapeutic methods[76], such as gene therapy and protein replacement therapy[77]. Quite an extensive protection as you can see, and that is what has enabled them to be the exclusive provider of screening tests for hereditary breast- and ovarian cancer. To cover one's bases this way is not uncommon or unlawful. But the broad scope of the patents and the way Myriad has used them have caused irascible feelings worldwide.

Genetic testing is particularly important when cancer runs in families. The test can provide answers as to the individual predisposition by screening for mutations in these genes, and the results will assist in risk reduction and early detection. It can also determine what level of risk there is for the cancer to return in patients that have already had cancer. MG has applied a strategy that includes refusal to grant any licences to the screening methods. Since MG has the exclusive rights to these tests they are able to prevent tests from being performed anywhere but in their labs in California or in one of their designated laboratories. That has in turn led to an increase in the cost for these tests, from 17000 SEK to 25 000 SEK per test in Sweden for example.

MG has protected all of their patents very aggressively. From their own point of view they have not done anything to prevent future research in this area. They claim that since everyone can get their test analysed at their facilities there is no obstruction of research or treatments. But their statement does not take away the fact that research work is indeed prevented and that clinical trials cannot be performed independently. Since MG do not issue any licences no other tests that use these DNA sequences or that detect the certain proteins that the sequences produce, can be developed. This creates problems since it is highly unlikely that their test can identify all possible mutations that can cause the hereditary cancer[78]. Even if MG continue to perform extensive research it will be hard for a single company to identify all unknown mutations. If a large number of researchers were conducting research and screening and analysing tests it would be more likely to come about. In the current situation better tests will hardly be developed. And if these genes turn out to be involved in other diseases, research on these will be prevented as well.

The appropriations of MG's patents have been controversial from the start. Immediately after the patents were drawn up they were protested against, and the 18th of May 2004 the EPO decided to revoke the patent for the BRCA1 gene on the ground that it lacked inventive step[79]. MG has made a statement that they will appeal the ruling. The new verdict might change the position previously taken by the EPO. The broad patents demanded by the pharmaceutical companies will perhaps be more restrictively granted now[80].

Another problem created by exclusive rights to screening tests occur when the patent holder also manufacture pharmaceuticals to fight the disease in question. There are great variations in how well drugs work on different individuals and it is possible to determine how effective the drug will be for an individual with a genetic test[81]. But these tests are not being developed because if the drug was to help only a few of those affected by the disease, the company's sales would decrease a great deal. This is a sad fact that is not only true for breast- and ovarian cancer but for all hereditary diseases.

[76] Experimentundantaget – behövs en förändring?, Ann Sandmark page 39
[77] Protecting and Transferring Biotech Inventions, H.H. Lidgard et al page 129-130
[78] The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs, L.B. Andrews page 11
[79] "Myriad/breast cancer" patent revoked after public hearing , EPO Press release
[80] TT, Göteborgsposten 2004-07-09
[81] The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs, L.B. Andrews page 12

Another aggravating factor is that there are no requirements for approval of genetic screening tests and these can be of a truly poor quality and still be the only alternative available for twenty years or more. Some of the screening methods can only confirm 20% of all possible mutations on a disease carrying gene[82]. The patent offices do not perform any quality checks and the exclusive right is granted no matter the quality. This does not inspire respect for the system. I maintain that people's health needs are ignored by this state of affairs and traded for the profit maximization demands of the industry.

Myriad Genetics is far from the only company that utilize their rights this way. A study conducted in 1999 shows that diagnostic tools are being licensed exclusively in most cases[83]. An illustrative example is the test for a rare genetic disorder called Canvan's Disease. The disease causes the myelin sheeting of the nerves in the central nervous system to dissolve and it affects babies. Parents to children with this disease jointly donated tissue samples to the Miami Children's Hospital in hope for new treatment and improved screening tests. The researchers were successful in developing a new test. But instead of making it readily available they forced laboratories to cease conducting the tests since they were seeking to licence the test exclusively[84]. After massive criticism they have at least cut the prices in half.

These are things that will happen when broad patents are issued on diagnostic tools. It is indisputable that complicated tests should be patentable. Many diseases involve numerous genes connected in complex ways and we learn more about these every day. We also learn more on how acquired mutations cause disease. Increased ability to perform these tests depends on lengthy and costly research and the results should be patentable. It is significant that the inflow of money is secured and that is ensured through intellectual property rights and production- and licence privileges. But it should in my view only be possible to patent the technological advances, not the information contained in the genes. It would then be possible to develop competing and more advanced tests which would be beneficial for us citizens and the overall progress. Accordingly it is necessary to reduce the scope of the patents for diagnostic-tools and only grant protection for the tests themselves.

7.2 Research-tools

Research-tools are DNA sequences that have no known therapeutic or diagnostic use, instead they are used in research to identify, characterize and develop products. They are not any part of the process of the drug manufacture, instead they generate data and information used by companies when developing target drugs et cetera. Examples of research-tools are screening techniques and biological compounds that have some useful properties. The patent owners are often granted strong protection for an identified gene sequence that in many cases only has a theoretical field of application and the tools are often discovered by routine work. Their patentability has been heavily questioned.

The biotech and drug discovery companies patent research-tools to an ever increasing extent. The patents are issued very early in the research process and generate most income by being licensed and to develop target drugs[85]. Companies derive competitive advantages when finding better and more efficient tools, and the patents also make it possible to create obstacles for other companies. As a matter of fact, the principal objective for patent owners seems to be to block competition and to use them as defensive weapons. All companies and public institutions are at

[82] The Ethics of Patenting DNA, Nuffield Council on Bioethics page 48-52
[83] Genetic Inventions, Intellectual Property Rights and Licensing Practices, OECD Paper, page 16
[84] Genetic Inventions, Intellectual Property Rights and Licensing Practices, OECD Paper, page 17
[85] The Ethics of Patenting DNA, Nuffield Council on Bioethics page 56-57

risk of infringing several of these patents while developing new drugs and/or conducting research.

Many of the research-tools are in essence the foundation for future innovation and development. Some tools, such as the hybrid-DNA technique and human embryonic stem cell lines, create whole new research platforms and have the potential of being developed in numerous directions[86]. It will be hard, if not to say impossible, for a single company to use the tool to its fullest and follow all the different paths that are possible. The advocates in favour of issuing strong, broad patents on research-tools maintain that the owners will licence the technology out in situations like these and more research paths will subsequently be followed. But as we have already established, transactions do not always run smoothly and are often costly. The universities and other non-profit institutions may not be able to afford the fees and the benefits will in these cases not exceed the costs. There are additional problems when owners impose reach-through rights on the licensees, but I will get back to that subject below.

It is necessary that patents on research-tools are not allowed to be too wide in scope and are widely licensed or they will most definitely block future innovation. The ideal would probably be to only allow proven specific uses to be patented. Because automated genome-decoding machines are performing the identification and sequencing of genes it should not be possible to patent mere results from this process. In my view the information cannot be considered to have sufficient inventive step or utility and it should not be possible to restrict others from using this kind of information.

7.3 Gene therapy

There are tens of thousands of different mutations that can cause the same disease within a single gene. Recent research efforts are aimed at repairing or removing the mutated sequence and interchange it with a faultless sequence[87]. This would enable us to cure spinal cord injuries, Alzheimer's disease and other illnesses. The research work is time-consuming and costly but very important since it would enable us to cure all feasible mutations. To grant patent protection for gene-therapy methods does not pose a problem and will not obstruct future research. In contrast it will be necessary since the development will involve pioneering work that will have extensive utility. There are no gene therapy products for humans on the market yet, but great efforts are being made in this area. By now gene therapy is commonly used in plants and animals, but it still remains an imprecise technology.

Problems occur when patent protection is routinely granted for the use of a DNA-sequence in gene-therapies though. Embryonic stem cell lines are for example being patented for this purpose. They are important since they have the potential of becoming *any* cell but exactly how this is done we still do not know. As discussed above it is in the present-day situation sufficient to state that a DNA-sequence is theoretically possible to use in gene-therapy to receive protection. These inventions lack inventiveness and are in all fairness no inventions at all. These patents will only serve as an impediment for development of real, functioning gene-therapy methods and should therefore not be allowed.

[86] Genome Patents: A Case Study in Patenting Research Tools, by Arti K. Rai Academic Medicine, Vol. 77
[87] The Ethics of Patenting DNA, Nuffield Council on Bioethics page 61

7.4 Therapeutic Proteins

Therapeutic proteins are what they seem to be; artificially made proteins that are used as pharmaceuticals. The therapeutic value of proteins has been known for a long time. Previously it was only possible to produce proteins by using tissues from humans and animals, but since the mid-1980s it has been possible to produce therapeutic proteins outside the body on a large scale. When the old techniques were used many of the proteins were purified and this makes them unpatentable today. Thus companies started to patent the genes that code for the therapeutic proteins and the technology that enable the production instead. The patents cover both the specific DNA sequences and the structures of the proteins[88]. There is a large interest in these products and they play an important role. As opposed to other gene patents these patents are possible to invent around because it is possible to give protein new and/or improved qualities that can in turn be patented.

The production of therapeutic proteins on a large scale is quite expensive. Therefore researchers are trying to find more efficient and inexpensive ways to produce them. The object in view for current research is to create better bioreactors. As I mentioned briefly in the beginning of the paper it is possible to use cows and pigs as reactors. By genetic manipulation a human gene fragment is combined with the gene fragment that promotes protein production in the animal. That DNA fragment is then inserted into a fertilized egg where it becomes part of the nuclear DNA. The egg is put back into the uterus of the cow or pig resulting in genetically modified animals being born. These animals later start producing milk that contains a largely increased concentration of the desired protein[89]. This method of production is not completed and is not on the market yet but will probably be introduced in the near future.

As you probably remember there are at least 100 000 primary forms of human proteins, and numerous additional modifications of these. The search for the gene sequences that code for the proteins that have potential therapeutic applications, and thus the greatest market values, is in progress all over the world. An example of what is being done is the investigation of the family of Disintegrin-proteins. These proteins were originally found in snake venom. They have the ability to inhibit adhesive cells on the surface of tumor cells, fibroblasts etc from sticking together[90]. It is considered likely that they will have multiple therapeutic applications in areas such as cardiovascular disease, tissue remodelling, tumor suppression and growth control.

Therapeutic proteins probably ought to remain patentable. When companies have developed a therapeutic protein they should be granted the exclusive rights over this product and to the use of the gene sequence that their product is based on. But it is important that they are only granted a relatively narrow scope and that there really is a practicable use, in other words, that there is a significant utility before the patents are granted. Since DNA-sequences can code for many different proteins it will be unsatisfactory if the patents are granted for all uses of a particular sequence.

There is obviously a lot more to say about the different subgroups of biotechnological inventions than there is room for in this paper. There are also dimensions that I as a lay person probably do not understand as well. But I think that I have given you enough information for you to realize the width of the issue at hand.

[88] The Ethics of Patenting DNA, Nuffield Council on Bioethics page 62-63
[89] Production of Therapeutic Proteins by Genetic Engineering, Duane T Gish
[90] ZymoGenetics Receives U.S. Patent on ADAM33 Protein 7/18/2002, ZymoGenetics Homepage

The conclusion I draw from all of this is the same as I made previously; the patenting has gone too far in some areas. The fundamental principle stating that information in itself cannot be patented needs to be brought forward; it should not be possible to patent things that are just created by skill. Especially since automated DNA sequencers have taken over the job it seems an injustice to be able to exclude all others from using the information. If the underlying information and discovered facts were unpatentable all research and development work would be facilitated. It is the applications that ought to be patentable, not the naturally occurring basic biological compounds.

8. The Database Directive

Lately additional ways to protect data and research results have been created. These are forms of protection that fall somewhere between patent and copyright protection, e.g. the plant-breeders right and the sui-generis protection for non-copyrightable databases. Remarkably enough the protection for databases might also affect the biotech industry by further restricting access to scientific data. I will thus briefly examine the Database Directive[91].

In Sweden we have had a general sui-generis protection for a long time. It has protected producers of catalogues and other similar tables of data. It was created to protect the producers' economic interests, and it still does. The only criteria for the protection to arise are that some kind of data or information has been gathered and compiled into a collection. There are no requirements of originality or on the selection of data. It is possible to use this right to protect for example pure facts or algorithms[92].

When DNA information, or any other information, is collected and processed it is possible to get copyright protection for it. After the information has been published the included information can be used by anyone free of charge. If the material lack in originality and characteristics the material is however non-copyrightable, but it is still possible to receive sui-generis protection if the information is put into a database.

The basis for the sui-generis protection can be found in Art 7.1 of the database directive. It states that all member states "shall provide for a right for the maker of a database which shows that there has been qualitatively and/or quantitatively a substantial *investment* in either the obtaining, verification or presentation of the contents *to prevent extraction and/or re-utilization of the whole or of a substantial part*, evaluated qualitatively and/or quantitatively, of the contents of that database"[93]. It continues with two definitions; "'extraction` shall mean the permanent or temporary transfer of all or a substantial part of the contents of a database to another medium by any means or in any form" and "'re-utilization` shall mean any form of making available to the public all or a substantial part of the contents of a database by the distribution of copies, by renting, by on-line or other forms of transmission". The right applies irrespective of the fact that copyright or any other protection is granted as well.

The reason I bring this up is because the sui-generis protection can place serious obstacles in future research and innovations way. When knowledge is further privatized there might be an even greater shortage of information and knowledge that can be further developed. The Database Directive creates an opportunity for researchers to publish their discoveries and results in protected databases and, contrary to information that is being published the traditional way, it is possible to restrict or completely prevent the use of the data published in a database[94]. In addition, the protection is even wider than for copyright. When copyrighted work has been brought onto the marketplace the right has been consumed, but that is not the case for the content in a protected database. It is permitted to restrict access by requiring all users to conclude an on-line licensing agreement or accept certain conditions before access to the information is admitted[95]. These and other forms of technical protection are often used and are unlawful to

[91] The European Community's Directive on the Legal Protection of Databases, 96/9/EG. The directive has been incorporated into Swedish law and can be found in 49§ of the Copyright law (Upphovsrättslagen).
[92] A Contractually Reconstructed Research Commons For Scientific Data In A Highly Protectionist Intellectual Property Environment, J. H. Reichman & Paul F. Uhlir page 29
[93] My italics
[94] A Contractually Reconstructed Research Commons For Scientific Data In A Highly Protectionist Intellectual Property Environment, J. H. Reichman & Paul F. Uhlir page 19
[95] A Contractually Reconstructed Research Commons For Scientific Data In A Highly Protectionist Intellectual Property Environment, J. H. Reichman & Paul F. Uhlir page 28-29

circumvent. A new and very broad protection has thus been created for all private and public researchers. The protection lasts for a period of fifteen years. Since the only criteria for protection is an investment, it should be possible to extend the protection by making an update that involve an investment.

It is possible to use an insubstantial part of the data though. But it will be hard to determine exactly how much of the data that can be used for it to be regarded as an insubstantial part. Furthermore you cannot use the part repeatedly or systematically or the exception will not apply. There is also an exception for "illustrations for teaching and scientific research". But this just means that it is possible to look at part of it, and you cannot use and/or include the extraction in your own work[96]. The sui-generis protection will presumably create an even stronger protection than copyrights and patents grant. Despite the fact that the directive has been in affect for many years there have been few recommendations or statements regarding the interpretation and the extent of the protection. How it will affect future innovation is anybody's guess but considering how universities and individual researchers have responded to the possibility to patent their work it is not farfetched to predict that they will use this possibility as well. The sharing-ethos will than be even more excavate and access to genetic information will be further limited, bringing delayed progress and increased transaction costs in its train.

[96] A Contractually Reconstructed Research Commons For Scientific Data In A Highly Protectionist Intellectual Property Environment, J. H. Reichman & Paul F. Uhlir page 34-35

9. The pro patent arguments

The biotechnological industry has always demanded legislation that provides sufficient and adequate protection and warns that no one will be willing to invest in R&D without far-reaching possibilities to receive protection. The pressure that the industry has brought to bear has so far been successful and current systems authorize extensive patenting. These have in turn caused a large increase in the number of patents on upstream innovations. The broad upstream patents have been a powerful motivator for R&D efforts and they give upstream companies a greater control and bargaining power that enable them to create successful collaborations with downstream developers. The universities have also started to commercialise their results to a much larger extent and downstream developers extend their operations to include research and development.

The industry is right to a large extent. The development processes, that begins with an identification of a biological compound or process and hopefully result in a protected invention, is lengthy and expensive. It has moreover been asserted that the patents do not always fully compensate for the R&D costs preceding it which makes it hard to recover the costs. The uncertainties in this regard speak in favour of issuing strong, broad patents. Furthermore, broad patents do not necessarily prevent multiple research paths since the owners will be free to issue licences that enable the pursuance of different research paths and they have the possibility to enter into licensing arrangements with multiple downstream companies. Initial discoveries can also be quite broad making the "spill over" information useful for competitors and this information will in addition contribute to the collective technological progress.

But the industry is still far from being altogether right. In a field where cumulative innovation is necessary it is not sufficient to say that multiple licensing is possible in theory. Historically it has been proven that effective multiple licensing is hard to achieve. The American National Institute of Health (NIH) established in a survey that licensing within the biotechnology, pharmaceutical and academic research sectors are associated with high transaction costs and an inability to conclude licences [97]. If both negotiating parties consider a technology to be of extreme importance, the arrangements are more easily made but innovation stemming from low value technology is abandoned most of the time. This means that many feasible projects never come to be and it is hard to attain effective licensing and it often involves very high transaction costs.

Moreover, competition is often regarded to be essential for innovation and the largest public-good in the long run. When several R&D paths can be followed there will be more creative early-stage research which will generate innovative results. An even stronger argument for opening up the market to competition is that the possibility to patent end-products is without limit.

Many advocates of patenting basic biological compounds and processes justify their position by maintaining that patents do not grant any ownership. It only renders a temporary exclusive right to use an invention. They consider patents to be the sole blowtorch for the overall progress and a secure development. As a law scholar I agree with the fact that patents in many aspects are very useful tools, and that private companies, universities and other researchers and scientists should be able to profit from their efforts. The heavy patenting of biotechnology has for instance helped keeping smaller companies alive until they have developed a final product and patents are regarded as guarantee warrants for a successful business and thus help these companies acquire venture capital to complete their products. But to say that patents do not result in a situation very

[97] The survey was made in 1997 and 1998. Fostering cumulative innovation in the biopharmaceutical industry, Arti K. Rai p.7

similar to ownership is absurd. The characteristics of ownership are that it involves the right to use and sell something and also denotes a right to exclude others from using it. All of this holds true for patents as well. The only difference is that the patent rights expire after 20 years.

Due to the extensive demands on, and costs for, animal research, human clinical trials, unsuccessful trials and medical approvals before drugs etc are approved the development of pharmaceuticals is far more expensive than the identification of genes, and I do not question these patents. It is when the patents system is being used for purposes that it was not intended for that the problems start. The incentive is for example not necessary for progress that only requires inexpensive decoding and identification. Isolated DNA sequences and proteins are furthermore not useful in themselves and it is not these products that generate the most income. It is when the knowledge is used in further developments that really profitable products are made. The benefits from these elementary discoveries will thus be put to better use if they are free for all to use.

10. Trends within the biotech industry

10.1 Increased collaborations

Historically there has been a distinct demarcation between the research done at biotechnology companies and at the pharmaceutical companies. This does not hold true anymore. Today pharmaceutical companies do not only focus on drug development but conduct research based on genetic and proteomic information as well. The need for genetic information has served as a basis for an increase in the collaborations between biotech and pharmaceutical companies. The co-operation has gone beyond licensing and today also includes widespread research collaborations and strategic alliances. Sometimes the companies even integrate, i.e. pharmaceutical companies move upstream by launching research laboratories and/or the biotechnology companies move downstream into clinical R&D[98]. The agreements and alliances are often formed very early in the research process. It is not uncommon that they involve early-stage research, such as identification of targets for drug development in a particular disease area or to develop new compounds. It is commonplace to share the costs for pre-clinical and clinical R&D as well as sharing the revenues from the final downstream product.

10.2 Broad patents

Generally applicants have a tendency to submit patent applications for very broad patents, especially for inventions that are still incomplete, and the descriptions are often meagre. To receive as wide patents as possible it is common to include numerous analogue compounds that are assumed to be practicable[99]. Broad patents that confer exclusive privileges are obviously a strong incentive for new development because of the large benefits. They also allow companies to coordinate their development efforts, thereby reducing duplicate investments and making the development more prolific. This effect occurs because all potential developers have to be in contact with the owner of the patent who than has the opportunity to bring about information exchange. But the exclusive privileges can also be misused and anti-competitive situations will most certainly arise and the strong protection will lead to higher transaction costs, a transfer of publicly funded research to the private sectors, longer waiting periods for new innovations and the social costs run the risk of becoming exceedingly high. These facts demonstrate the need for restrictions on the content and scope of the patents.

10.3 Monopoly creation

To the best of my knowledge there has not been any studies made determining what kind of market that will facilitate innovation the most[100]. But in a report made by the Swedish government it is settled that there is a strong possibility that monopolies may arise due to biotech patents[101]. Even if the patents are quite weak they still have the capacity to prevent innovation through monopoly creation and companies are able to misuse their dominant positions.

10.3.1 Excessive Litigation

An example of anti-competitive behaviour is when companies holding key patents protect these by going after all prospective infringers. Some companies make frivolous actions and are able to shut down competitors by this procedure. The overall cost for patent litigation is extremely high, annually about $1 billion is spent on patent litigation in the U.S. alone[102]. The claim damages for

[98] Fostering cumulative innovation in the biopharmaceutical industry; Arti K. Rai p.3
[99] Experimentundantaget – behövs en förändring, Ann Sandmark page 24
[100] Fostering cumulative innovation in the biopharmaceutical industry; Arti K. Rai p.7
[101] "Att spränga gränser – bioteknikens möjligheter och risker", SOU 2000:103, page 33-34, item 10
[102] Patent pools and the anti-trust dilemma, Steven C. Carlson page 11

patent infringements are also extremely severe and the outcome is uncertain due to the difficulties in defining the scope of the claims and the difficulties interpreting them.

For SME's a prosecution can be devastating for the whole business, irrespective of whether they really do infringe or not. Small companies usually do not have the resources to cope with the costs and if they oppose the charges, goes to court and subsequently wins, they might lose their business anyway due to the costs of the litigation process.

Furthermore, to bring action against companies that perform excessive litigation is not simple. In Europe it is necessary to prove that the action taken has no merit, and that it only serves "to harass the opposite party" and also that "it is conceived in the framework of a plan whose goal is to eliminate competition"[103]. In the US the plaintive has to prove that the lawsuit has no qualification and that the suit is only being used as a tool to interfere with their competitors[104]. These requirements are very hard to prove and fulfil. This state of affairs obviously makes it even harder for competitors to protect themselves from companies in a monopoly situation.
I believe that it is necessary to review these regulations and make it possible for the subjected companies to take appropriate countermeasures.

10.3.2 Monopoly pricing

Patents, i.e. temporary monopolies, are granted because the owners should be able to profit from their investments and recoup the costs for research and development. Because of the temporary monopolies companies are able to set the market prices higher than what the competitive price would be and they can also limit the total volume of sales. The World Health Organisation (WHO) has for example estimated that most of the patented medicines are sold at 20 to 100 times their marginal cost. This is an expensive way of paying for research but in a perfect world the large profits would bring about new innovations and products that society as a whole would gain from in return. But in the biotech industry this would probably not be the case because the necessary conditions are not fulfilled, i.e. there will not necessarily be any reduction of the production costs, improved production methods et.c. since there is no competition on the market due to the specific properties of genomic inventions. Biotech patents with very wide scopes are in most cases impossible to improve on if the owners do not sanction use of the original patent and patent owners might be reluctant to licence the technology for this particular reason.

10.3.3 Utilization of Grant-back clauses and Reach-through rights

In the biotech sector collaborations with different parties are often necessary to gain access to technologies and products. When collaboration is not necessary or wanted, licence-agreements are utilized. Some of the licensing practices extend the scopes of the patents beyond what was intended and may hinder competing products from being developed. This come to pass when the owners of patented material use their monopolistic advantages to restrict access to the inventions by merely license them to users that agree to give them a share of future development and/or earnings.

One way to do this is to include grant-back clauses in the licence agreements. When licensing out research-enabling technologies the licensor demands a right to all future inventions and improvements that derive its origin from the patent. The grant-back is often exclusive and sometimes ownership is even demanded. This way the owners can remain in control of the technology and does not loose competitive strength or market shares and they also ensure a piece

[103] Article 6 and 13 European Convention for the Protection of Human Rights and Fundamental Freedoms
[104] Protecting and Transferring Biotech Inventions, H.H. Lidgard et al page 175

of future earnings[105]. Many consider grant-back clauses to unjustly overcompensate the owners' contributions. When e.g. research tools and platform technologies are licensed extensive work remains before any marketable products are completed and it does not seem right that the tool-owners shall own title to these later developed technologies. Additionally the licensees will have a reduced incentive for making improvements to the technology and research will be delayed.

Another strategy frequently used by companies is to include reach-through rights in the license agreements. In this situation licensors do not require any fees for the use of the patented technologies; instead the licensor is obliged to pay royalties if and when a product is put on the market. The licensor takes a greater risk by using these kinds of agreements, but the potential payoffs are larger.

Another way of imposing reach-through claims is to require that the licensee reports all research results arising due to the licensed invention to the patent owner, who in turn is given a right to determine whether the results should be further developed and commercialised or abandoned. In the licence agreements for the Onco-mouse and the Cre-Lox technologies such claims are included. These two patents are owned by DuPont Corporation. Well, actually Harvard owns the Onco-mouse but DuPont has an exclusive licence to it, and rights to sub-licence, since they sponsored the research[106]. Both patents are for genetically modified mice that can be used in research. DuPont demand that all results derived from the use of the mice is reported back to them and approved the above mentioned way. This gives DuPont an extreme power and a total control over all future research and this right goes well beyond the scope of the patent.

Even in this section it is necessary to bring up patents with very wide scopes. When patents are broad enough to cover future discoveries and products the owners do not even have to enter into license agreements to make money from other companies' efforts. They can wait and start their bargaining when a product is ready to be put on the market, thus companies that own research-tools can be sure to profit from a wide range of products in the future.

Needless to say, these trends cause concern. Under the current patent system it is increasingly important that licences are readily available and distributed effectively. The fact that owners of early stage research tools and core technologies have the ability to entirely block research or at least determine its direction by not allowing licensors to follow up on their results and progress is yet another evidence of the current systems insufficiency.

[105] Reaching Through the Genome, Rebecca S. Eisenberg, page 107-109
[106] Can patents deter Innovation? The Anticommons in Biomedical Research, M.A. Heller & R.S. Eisenberg, page 699

11. Partial emendations

Evidence that gene patents are slowing down innovation and product development is mounting, but there is no consensus on how to solve the problems. Many are of the opinion that the market should be left alone and that it thereby would regulate itself. I am not convinced that that would be the best solution. If this action was to work it would take a complete elimination of all transaction costs, that no businesses applies any strategic behaviour and that there is no competition between companies, they should instead have profound collaborations with one another. But it is a utopia that this scenario should ever occur. Everyone wants to have access to basic research results and tools for free or at very low cost but at the same time they all wish to profit from their own inventions.

Recently misgivings that go beyond moral concerns and legal issues have come up for discussion as well. Many are convinced that public health and the medical care systems are seriously harmed by the current patent system. The overpowering emphasis on the individual contributions made by researchers and companies has been criticised as well. On account of these complaints policymakers all over the world are starting to investigate different options of how to solve these problems. There have been many proposals for possible improvements but no complete solutions have been presented. I have already pointed out weaknesses with the current system, and observed what improvements and adjustments that could be made. I will now take a look at some additional emendations that have been presented by different councils, commissions and legal advisors.

11.1 Harmonised International regulation

I must start off by establishing that there is a need for harmonious international regulations. Most companies dealing in biotechnology are transnational and the different parts of the world get more and more interdependent of one another and harmonious regulation is of utmost importance. Harmonised regulation would for instance facilitate negotiations, transfer of knowledge, the development of model contracts and so on. Efforts such as the OECD's formulation of best practice guidelines for the licensing of genetic resources are praiseworthy and will facilitate use and distribution.

11.2 Altered patentability requirements

Another aspect that I have mentioned previously is the need for a more rigorous application of the patentability requirements. Patent protection and restricted access is not motivated when there is no innovative achievement or true utility. A recommended solution is to use the utility requirement to block much of the patenting made on upstream innovations. If it was to be used more strictly inventions that do not have any specific therapeutic uses could not be patented. This would prevent the patenting of gene sequences of unknown functioning, making it possible to conduct further research on the entire gene. If in addition the granted patents on, for example, a gene sequence were to be defined narrowly they would not prevent later patenting of other sequences or of the full-length gene.

11.3 Open access databases

A solution to the accessibility problem could be the creation of open access databases. The obvious advantages with these are of course that no fees are involved. An example of such a database is the National Centre for Biotechnology Information's (NCBI's) database GenBank[107].

[107] Just the facts: A Basic Introduction to the Science Underlying NCBI Resources, NCBI Homepage

The GenBank consists of collected and mapped ESTs contributed by both private researchers and large institutions. In the database there are thousands of ESTs which are matched with their specific DNA sequence and its function. The knowledge facilitates the mapping of chromosomal sites and the discovery of new genes. Thus the database is a powerful research tool, available for everyone. The site has e.g. been helpful in the identification of the genes responsible for colon cancer and Alzheimer's disease.

Knowledge platforms like these have been extensively used within the chemical industry and have been proven to result in reduced transaction costs and duplication work is possible to avoid to a large extent.

11.4 A reconstructed experimental exemption

Another partial solution might be a reconstructed experimental exemption. Many find that the present system is not well adapted to its purpose but the industry worries that a more express research exemption prescribed by law would reduce the incentive to perform research and develop new products.

The European Patent Convention (EPC) already sanctions experimental use of patented inventions. It is permitted to use an invention for private purposes as well as in professional research efforts and reverse engineering. It is possible to perform experiments on the inventions themselves, and use them in work aimed at developing and improving the technology and to find other areas of application or indications for it. If the development work is successful the new inventions can in turn be granted patent protection[108].

In the US there is no true experimental exemption but through case-law an exemption of sorts has been established. According to the exemption it is not possible to conduct research aimed at improving or further developing an invention; it is only allowed to verify or falsify an invention or to perform so called "philosophical experiments" Research on the invention is thus allowed, but not research using the invention[109]. Hence to avoid liability for infringement it is only allowed to carry out experiments "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry". If a patent owner has more than one patent it is not allowed to use one of them to examine another. This causes problems when information in one patent is needed to examine another patent or when one of them is a research tool, because it is not possible to verify or falsify the results or the granted patent[110]. Licences are required to conduct further research and researchers are surrendered to the good-will of the patent owner. The amount of licences that are issued is probably dependent on whether the parties are competitors or not.

When genes, screening methods and laboratory and research tools are getting patented it is obviously possible to withhold them from the research community and to prevent both commercial and non-commercial research without a license[111]. It is principally the patents on research tools that create problems. As repeatedly said; research tools are mostly used in the very early stages of research, for example to identify chemical entities, to identify and adjust different properties, as a measuring instrument et.c. Currently it is only permitted to develop the tool itself, not to use it per se. An illustrative example of how research might be restrained is when a certain protein has been patented as an indicator for X, but it might also work as an indicator for

[108] Gränser för genpatent m.m.– kortversion av lagrådsremiss
[109] Patents and experimental use, Australian Advisory Council on Intellectual Property page 2-3
[110] Experimentundantaget – behövs en förändring, Ann Sandmark page 29 & 35
[111] Protecting and Transferring Biotech Inventions, H.H. Lidgard et al page 162

Y. The development of the latter is than obstructed because access to the tool is restricted. Obviously patents with wide scopes are an aggravating factor in situations like these. The research exemption does not allow further research to be made even though the subsequent results might be patentable. If the patent owners do not grant any licences the only option is to try to get a compulsory licence. I will address compulsory licences below.

A suggested partial solution is to introduce a more extensive public research exemption that would allow non-commercial research with genetic information. But even if such an exemption was included problems would remain since it is hard to draw the line between commercial and non-commercial research and the two objectives often coincide with one another. The exemption would thus be quite narrow and would not solve the major difficulties.

Current design and interpretation of the experimental exemptions are not in line with the objective of the patent system and an effective allocation of the resources is not always achieved in Europe and in the US. The experimental exemption derives its origin from the fundamental principles of patent law and aims at promoting innovation by way of knowledge distribution, but that objective is not fulfilled. Additionally, the written descriptions in the patents are often meagre which makes it increasingly difficult to learn anything from them. It will be necessary to increase the scope of the exemptions to comply with the fundamental patent principles and to ensure an effective allocation of the limited genetic resources. Wide patents in combination with narrow experimental exemptions effectively block many research efforts and this problem has to be addressed in international forum.

11.5 Compulsory Licences

Many of the new drugs that are being developed today are remedies for diseases that are influences by multiple genes or proteins. Notwithstanding the breadth of the patents, downstream developers will have to receive licences from multiple patent holders. This opens up for a serious limitation on the competition. Additionally some patent owners refuse to license their technology, or grant exclusive licences, and the research exemption is often of no help in these situations. On occasion it might therefore be necessary to challenge the actions of companies that misuse their monopolistic privileges and it has been suggested that compulsory licensing might prove useful. Presently it is possible to receive compulsory licences when a patent is not exploited or when companies misuse a dominant position. This opportunity is seldom used though.

Compulsory licensing is for instance regulated by TRIPS. The agreement lay down rules that governments have to follow before issuing compulsory licences. These mainly concern "adequate compensation to patent owners" and there are demands for negotiations to ensure that licences are issued on "reasonable commercial conditions and terms[112]". Compulsory licences can be issued to counteract anti-competitive practices, for dependent patents and for public non-commercial use. If there is a "national emergency or other circumstances of extreme urgency" the right is extended to private sector uses. What is considered to be a situation like that is left up to the governments to decide.

The Biotech Directive addresses compulsory licences in Chapter 3 Art.12. Unfortunately the article only mentions "plant variety rights" and says nothing about other types of biotechnological inventions. To receive a compulsory license the applicant must hold a patent that is dependent on a previous patent, and the new invention must "constitute a *significant*

[112] Statement on Essential Inventions to the Commission on Intellectual Property Rights, Innovation and Public Health page 5-6

technical progress of *considerable* economic interest"[113]. Thus it is quite hard to fulfil these criteria. Since I do not include plant variety rights in this paper I will not discuss the article in any depth, but it is still interesting to bring it up since it hints at what the current attitude towards compulsory licensing for other biotech inventions is within the EU.

In Europe the first situation in which a compulsory licence can come into question is when an invention is insufficiently exercised[114]. What level of utilisation is deemed as a reasonable extent is determined on a case to case basis. National utilization is placed on equal footing with exploitation within the EC as well as imports from states that are affiliated with the World Trade Organization (WTO). When imports, at least in theory, cover the needs the exploitation is considered sufficient[115]. But when a patent holder for instance do not grant licences to perform genetic tests and demand that samples be sent to their country of origin for screening, compulsory licensing may be actualized. That can also be the case when improper conditions are used or if there is only limited access to a patented product. In cases such as the one with Myriad Genetics it could perhaps be argued that since there are no labs in Europe they cannot be considered to practice the invention here. In consequence a company that wish to perform BRCA-screening in Europe could, at least in theory, be granted a compulsory licence. The fact that MG has been able to set monopoly prices and do not grant any licences will speak in behalf of a compulsory licence.

The second ground for granting a compulsory licence is when there is a pronounced public interest[116]. What comprise such an interest is not clearly defined. The granting of compulsory licences is always restrictive and even more so in cases like these. To receive a compulsory licence for dependent patents it is required that the second invention involve "an important technical advance of considerable economic significance in relation to the invention claimed in the first patent". The holder of the original patent shall also have the right to cross-licence the new invention[117]. Obviously it is an arduous task to fulfil these criteria.

The biotech industry claims that compulsory licenses will create a lot of problems in the biotech industry. As always they warn that no R&D investments will be made if and when the patent rights are weakened. But this does not have to be true. In the US "R&D Mandates" have been used which guarantee that sufficient funds are contributed to further research. When the American government allowed parallel imports of medicines it was on the condition that the parallel traders contributed money to fund future R&D. This action actually generated larger reinvestment in research than when the market had liberty of action[118].

You would expect compulsory licences to get more and more common as more genetic inventions are granted wide protection, but that does not seem to be the case[119]. There could be numerous explanations for this but most likely it is due to the tremendous difficulties involved in fulfilling the criteria. Dependent patents very seldom involve such great improvements that they are considered to be of such a huge interest to the public that it motivates an issuance of a compulsory licence for instance. The issuance is also preceded by a long and costly judicial procedure which many applicants will have trouble financing. In reality it is probably much

[113] My italics
[114] The Swedish Patent law 45 §
[115] Gränser för genpatent m.m.– kortversion av lagrådsremiss
[116] The Swedish Patent law 47 §
[117] Statement on Essential Inventions to the Commission on Intellectual Property Rights, Innovation and Public Health page 6-7
[118] Statement on Essential Inventions to the Commission on Intellectual Property Rights, Innovation and Public Health page 7
[119] Protecting and Transferring Biotech Inventions, H.H. Lidgard et al. page 164-168

easier to infringe and hope for the best, or to start some kind of collaboration with the holder of the prior patent.

Compulsory licences can be a useful tool to avoid many of the drawbacks associated with gene patents though. If and when a developer has tried to settle the matter through negotiations with the original patent holder but have failed, and can show that the lack of a licence is due to strategic anti-competitive behaviour from the original holder, it should be possible to issue compulsory licences. This is particularly important when the patents have been inexpensive to develop or are a platform technology. If the downstream developers were obliged to pay fair royalties I believe that such a regiment would work. Besides, previous experiences have shown that the mere threat of compulsory licensing has served to drive down the costs of pharmaceuticals. Current legislation put too great demands upon the applicants making it difficult to fulfil the requisites. It is also possible for owners of patents to block or bury technologies altogether. It should be made easier to receive compulsory licences to a much greater extent than it is today and, as is the case with all of the partial solutions, the question needs to be addressed internationally.

11.6 Patent-Pools

Patent pooling arrangements have been suggested as a part of the solution to the access problems within biotech. Pools that are well adapted to their purpose are considered to have pro-competitive effects and promote innovation and faster product development by reducing transaction costs and integrating complimentary technologies. I envision that some kind of knowledge-pool would be useful for the innovation process.

The formation of pools occurs because there are some distinct ways that companies can derive advantage from them. Patent pools are principally created to clear blocking positions or as an instrument to resolve disputes out of court. This solution will particularly benefit the many small firms that cannot afford or survive severe litigation costs [120]. Sometimes cross-licences are used in their place but the pools have advantages that this solution does not have. Once the patent disputes are cleared the pools facilitate faster product development by preventing duplication work, by making the distribution of know-how more effective and by minimizing the risk of infringement litigation. All members in a pool will also benefit by the risks being divided and this ought to be a strong motivator for biotechnology companies since the risk of failure is high. The research and development efforts always result in spill-over knowledge that most companies do not have the ability to follow up on, but that can be useful in other companies work. Pools will thus give rise to more research-paths being followed and more results being further used and developed. They will also allow companies to specialise in their own particular area which will in turn also promote the overall progress of technology.

Another advantage is that licensees can get all necessary patents in a one-stop-shop. This will reduce transaction costs and presumably also reduce the opportunity to apply “hold-out” strategies. Without a pool a licensee might have received licenses to all necessary technologies besides one. The owner of that technology is in a position where it is possible to demand unreasonably high licensing-fees and shares of future profits. Provided that all related and necessary technology is included in a pool no one will hold this position.

[120] Patent pools and the anti-trust dilemma, Steven C. Carlson page 11

11.6.1 IP-Guidelines

Patent pools are more common in the US than in Europe. There are pools mainly within the radio/television-, hardware- and telecom industries[121]. Existing patent pools are slightly different from one another but there are some basic attributes they all share. In 1995 the US Department of Justice (DOJ) issued the *Antitrust Guidelines for the Licensing of Intellectual Property* ("*IP Guidelines*")[122] which include regulations for patent pools. While recognising the possible benefits, the guidelines also point out the fact that pools can be anti-competitive under certain circumstances. If a pool create monopolistic advantages by e.g. unfounded exclusion of certain companies it will not be approved, nor if the design of the pool discourages future research and innovation or if they affect prices or competitors on downstream products. I will continue with an examination of what is possible to do and how the pools are best worked out.

All licensors must grant non-exclusive licences to their patents, and shall be free to licence outside of the pool. Only technology that is deemed to be essential is allowed to be included and to work well the pool should have a technology standard that is well defined. Contributing pool-members either get their membership free of charge or have a set individual licence fee while non-contributing members shall pay a predestined fee. It is not permitted to require licensees to take package licenses or to include unpatented material in the license; in other words it must be possible to only license the necessary technology.

The allocation of royalties is either based on a set rate or on proportional contributions. There are often grant-back clauses included in the agreements but these are usually limited to essential future patents and licensed on reasonable terms. It is prohibited to require that the licensee assign patent which may be issued to the licensee after the license agreement is executed. It is not permitted to attempt to restrict the licensees' resale of a product either or to try to restrict the freedom to deal in other products or services which fall outside the scope of the licensed patent. It is permitted to require licensees to pay royalties on their future sales as long as they are related to products covered by the patents. Lastly the pool cannot set minimum prices on the licensees' products or restrict the licensees' sales.

Many of the pools are managed by a common administrator that is appointed by the patent holders and who handles administrative tasks such as signing up licensees, collecting royalties from the licensees, and distributing the royalties[123]. They also determine which technologies that is essential and ensure that the included patents are valid and not expired. Already included patents must also be reviewed continuously

11.6.2 Restricted competition

When the technologies in a pool are complementary the competition will not be limited. But if competing technologies are put into the same pool competition can be limited or entirely eliminated and this will in turn be harmful for the market. On that account governments need to monitor the pools to ensure that only patents essential to one specific technology are included in the pool.

[121] Experimentundantaget – behövs en förändring?, Ann Sandmark page 44
[122] Patent pools: A solution to the problem of access in biotechnology patents?, USPTO page 6, U.S. Dep't of Justice & Fed: Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property (1995)
[123] U.S. Dep't of Justice & Fed. Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property ("IP Guidelines"), 1995

The creation of a patent pool basically has the same effects as a horizontal merger[124]. A monopoly of sorts is created and holders can set prices and royalty rates. One could hence say that the guidelines for the pools are a departure from the anti-trust legislation. If companies gather numerous crucial patents they are able to monopolize an entire area within research and development[125]. When this happens in "regular" markets it is possible to counteract the situation using anti-trust legislation. For an emerging field, such as biotechnology, this is much more difficult to do. The reason for this is that it is much harder to define the relevant market for new innovations. There might not be any end-products at that stage and it is hard to predict the future market for the goods. When the research enters into the clinical testing phase it will be possible to determine the relevant market quite easily, but before that stage it is close to impossible for the government to know whether there are, or will be, any competing technologies developed.

Another problem with pools is that it is possible to deny competing companies access to them. This is a particularly large problem for biotech since most inventions are impossible to invent around. An aggravating factor is that there would have to be a large number of patents in a biotech patent pool and the more patents that are included, the harder it gets to avoid competition from being obstructed.

Yet another problem with patent pools is that they can shield invalid patents. Not all granted patents are valid and this is a big problem in both the US and in Europe. The problem will probably get more serious as the applications get more difficult to appraise and the prior art harder to evaluate[126]. The fact that patent offices have limited resources and sometimes even work on commission does not help the situation. Regardless of these facts, it is possible to minimize the risk of invalid patents if and when independent experts are monitoring the pools.

11.6.3 Biotechnology and patent pools

Still the pooling of patents might be a good solution. The biotech industry has limited resources that must be used efficiently and the most obvious advantage with pooling is the accessibility to DNA-sequences, nucleic acids et cetera. The owners of the basic genomic inventions do not have the ability to single-handedly attend to all results and patent pools could be a part of the solution to this problem and would also encourage cooperation. Pools could also originate a fair distribution of the basic biological building blocks.

Patent pools work very well in theory. But if we look at their history we can see that the creation of many of them has not come about until after the governments have brought pressure to bear on the patent owners. I think that it is unlikely that patent pools will be created within biotech. Considering the fact that the actors on the market are of varying sorts and size, and have very different objectives, the cooperation and/or cross-licensing will be complicated. Since most of the biotech inventions are impossible to invent around hold-out problems will also have to be tackled. Furthermore some companies will make more money by granting exclusive licences. There are also the uncertainties associated with future applications and the fact that research is very expensive. Patent pools usually only occurs when the parties have a long tradition of cooperation and when they are relatively homogenous parties and this is not the case with the biotechnological industry.

[124] Patent pools and the anti-trust dilemma, Steven C. Carlson page 3-4, 13-14
[125] Fostering cumulative innovation in the biopharmaceutical industry: The role of patents and antitrust, Arti K. Rai page 12
[126] Patent pools: A solution to the problems of access in biotechnology patents?, USPTO page10

The conclusion we can draw from this discussion is that if we are to make the most of the great potential that biotechnology offers, significant cooperation between the public and the private sectors will be required. Current practices present barriers to access and there is an urgent need to fine-tune the intellectual property systems. Access to important technologies can be ensured by approaches and concepts such as the ones mentioned above but other approaches such as anti-monopoly responses, publicly funded licenses et.c. should also be examined.

12. Moral and Ethics

Regardless what your personal views on patenting of biotechnological inventions are, you have been influenced by your own sense of morality and the culture you live in. What is considered acceptable in a society and what is not varies from time to time and from culture to culture and these conceptions are not static. What was once unthinkable, like a royal divorce, can later be an everyday event, and something that was frequently done, like the beating of a disobedient child, is not accepted today. This paper is obviously primarily concerned with a legal problem. It is an imperative necessity that laws are created out of consideration for a sustainable public development and reflects the current moral and ethics in a society or they will not be accepted or effective. Many concerned voices have been raised against any interference of ethics and moral in the discussion and development of biotech regulation. They say that these are two separate issues, but I strongly disagree.

The industry and other pro-patent advocates are of the opinion that the question of patentability should only include business considerations and the ethical and moral considerations should be held separate. If not, the discussion would become more complicated and it would also be harder to conduct business[127]. Accordingly the advocates maintain that patents should only be examined by a patent agency who shall determine whether the patents shall be granted or not. If and when a patent is issued it could be examined on an ethical basis separately if necessary and the decisions should preferably be handled by the domestic courts. I really find it hard to see any advantages with a solution like this though. The effect would be that patents that are approved in the primary instance could be considered invalid on ethical grounds later. Companies would consequently pay for patents that they later might not be allowed to use. I cannot see how companies will gain economically from such a regiment. The opportunity to challenge patents in different courts would result in increased insecurities and costs for litigation. Moreover it is highly doubtful that the national courts possess the necessary competence to evaluate what the possible negative impacts from these advanced biotechnological inventions would be. It will most likely be hard for them to make the appropriate judgements. I consider it a better idea, from an economical angel of approach as well, to incorporate some kind of ethical council into existing patent authorities.

It is furthermore an imperative necessity for us to meditate upon what values other than large market shares and profitability that should influence our legislation. If we disregard morality, common sense and human worth we are going to end up with a society that I do not want to be a part of.

12.1 Transgression of the law

That morality is important is reflected in many regulations. The TRIPS agreement e.g. allows states to prevent patenting of inventions that "threaten *ordre publique* or morality"[128]. Moral is in these circumstances defined as "the belief that some things are just and ideal and some are not". Not a very precise definition, but it can hardly be described any other way, and it mediates the fact that moral is not static. *Ordre public* is a protection for public security, individual's physical integrity and for the environment[129].

To put a stop to patents on inventions that are contrary to the moral conception in Europe, the European Community included an article in the Biotech Directive that determine what is to be

[127] Can Patents Deter Innovation? The Anticommons in Biotechnological Research, M. Heller & R. Eisenberg page 698-701.
[128] Art 27 TRIPS Agreement, The Ethics of Patenting DNA, Nuffield Council on Bioethics page 36
[129] The Ethics of Patenting DNA, Nuffield Council on Bioethics page 34

regarded as unpatentable subject matter. In article 6 it is settled that inventions whose commercial exploitation are contrary to ordre public or morality are unpatentable. But it also states that even though an invention might be prohibited by law or regulation it is not necessarily contrary to morality/ordre public. So basically patents can be issued and paid for since they are not immoral, but you still cannot use it since it is against the law. What on the other hand *is* supposed to be unpatentable on these grounds is unfortunately quite unclear and the article seems to be used very rarely.

The article was brought to the fore in the dealings with the onco-mouse patent. After some reluctance the Examining Division of the EPO applied the morality criterion in this case. To be able to do this they created a balancing test for the particular case [130]. The test was designed to weigh the pros and the cons against one another. The test took into consideration:

- The interest of mankind in providing remedies for dangerous diseases
- Protection against uncontrolled dissemination of unwanted genes
- Prevention of cruelty to animals

After considering these points the Examining Division came to the conclusion that the pros outweighed the cons and granted the patent. In connection to the ruling the Technical Board of Appeals also pronounced that an invention can only be considered "immoral if the general public would consider it so abhorrent that patenting would be inconceivable"[131]. What is to be considered as abhorrent enough is still unclear. Another obstructing fact is that the burden of proof is placed on the opponent and to prove that something is immoral seems very hard to do, particularly when considering what happened when Greenpeace tried to do that. They handed in protest-lists against the issuance of the onco-mouse patent but the EPO said that the lists did not indicate that the issue was against the moral in the area in question, despite the fact that the lists contained thousands of signatures.

The matters of judgement are still very vague which makes it hard to challenge patents on moral or ethical grounds and this section of the law is basically useless in its current shape. Clarifications and determinations need to be done if these sections of the law are to be used to any extent.

12.2 Cloning and human stem-cell research

When discussing ethics and moral it is impossible to leave out a discussion concerning cloning and research on human stem-cell lines. These issues are basically the only ones that have been publicly debated. Currently there is a global resistance to cloning, but it is likely that this position is about to change.

It is already possible to patent cloning techniques in the US and no cloning is unlawful per se. Several patents have already been issued in regards to the cloning of animals[132]. In Europe there is a stronger resistance to cloning than in the US. It is allowed to perform animal cloning, but cloning of humans is prohibited on the ground that it is contrary to *ordre publique* and morality[133]. There are no patents issued for the cloning of human beings as of yet, at least not to my knowledge, but I do believe that they are not too far away from being developed. The

[130] Intellectual Property Rights and the Life Science Industries. A Twentieth Century History, G. Dutfield page 161-162
[131] Intellectual Property Rights and the Life Science Industries. A Twentieth Century History, G. Dutfield page 161-162
[132] Protecting and Transferring Biotech Inventions, H.H. Lidgard et al page 80-82
[133] Art 6.2 (a) Biotech Directive

American Supreme court has already expressed their opinion on the issue. To them "procreation and the right to have offspring are fundamental rights"[134]. I know for sure that I do not agree with this standpoint. I do not believe that it is an absolute right for everyone to have children. There is also the question of the cloned children themselves. They have not been asked if they want to walk through life as an exact copy of their father or mother and it is impossible to predict how this will affect the mental health of these children. Of course I feel sorry for all the childless people, but their rights can never justify a diminished respect for the human dignity and the natural world and if human cloning is allowed it will definitely change the foundation of society and our values. Not many seem to consider this fact but I believe that is one of the most important ones. If we start seeing the right to have children as a fundamental human right, we will start to change our views on life completely.

The much talked about "designer-babies" will further enhance the view of children as objects that can be modified to please our wishes. The magic of life will be gone and imperfections and disease will not be accepted. The modified identity of these individuals will in addition be passed on to their descendants when gene-therapy has been performed. We have to ask ourselves what we are prepared to lose, and what do we have to gain? To me designer-babies are a cruel experiment and I truly believe that we need to stop and contemplate over what constitutes a meaningful life.

A related issue that has also been questioned ethically is research and patenting of human stem-cell lines. Presently it is possible to patent stem-cells in the US but not in Europe. These patents have great potential and are impossible to invent around. They will be extremely profitable in the future and that is why everyone wants them. But they have also been the cause of heated debates because of the needed research on discarded foetus' et cetera. The delimitation of what shall be permitted within this area and what shall not is extremely hard to make. Many diseases and defects are due to genetic damage and gene therapy will be able to cure these in the future. But where should we draw the line between life-style medicines such as the ones aimed at prolongation of life and the more accepted pharmaceuticals? Everything that is possible to do is perhaps not desirable.

12.3 What should the future hold?

Many religious- and other groups have lodged strong objections to the patenting of "life-forms" and consider it merely possible to discover genes, proteins and other basic biological building blocks, not to invent them. They consider them to be the creation of a higher power and as such they can never belong to any single person or company, they must belong to all of mankind. They believe that by turning "life" into patentable products we will drain life of its sacred value and nature. They call for a ban on these patents on the ground that the genes have existed in every single person, animal and plant for as long as we have existed ourselves. This view can surprisingly enough be supported by the current patent system in some ways, since the ordinary patent regulations have had to be evaded and the DNA itself have had to be transformed into a chemical to be patentable.

Notwithstanding your personal view on this issue I believe it is important to discuss the ongoing patenting of basic biological processes and building blocks or we risk loosing control over future development. Obviously it is not possible to foresee everything, but it is crucial to encourage an ongoing discussion. The general public should also be involved and need to be further educated.
Our understanding of biology is constantly increasing and new technologies are continuously developed. There are amazing new tool and ways to use biotechnology. We need to ponder upon

[134] Protecting and Transferring Biotech Inventions, H.H. Lidgard et al page 80-82

the use of these technologies and take this in consideration when making judgements and legislation. We need to be attentive if we are to avoid the dangers, particularly in regards to genetics.

12.3.1 Transhumanism

A frightening picture of future development is presented through the vision of the World Transhumanist Association (WTA). The Transhumanists are organised in a global network that is at work to promote and develop technologies "to extend human capacities". They advocate international legislation that fully authorizes any technologies aimed at the improvement of the human race such as techniques to "modify human nature, increase our lifespan and increase our intelligence"[135]. They want to shape what they see as a coming reality. The Transhumanists believe that the technologies used today, such as dental implants or artificial limbs, are our first steps to becoming cyborgs. They consider these inventions of no essential difference from future biomedical "enhancement technologies" such as silicone implants in the brain to improve our intelligence and memory, the development of neo-emotions that are adapted to our "modern situations, culture, and technologically-enabled existence" by extending and modifying the obsolete emotions that we apparently have to live with today. They also consider ageing a disease that medical science should cure and so on.

One of the founders of WTA, Natasha Vita-More (!!), has already designed one of these future humans which exhibits such useful add-ons as a sonar, a fiber-optic cable down the spine and convenient nanotech data storage in the brain. WTA even worry about how the future cyborgs will be treated. As artificially intelligent (AI) forms are developed they empathise that they cannot be treated any different from other humans since that would be racist, and "nobody should be discriminated against on the basis of their morphology or the substrate of their implementation". That the transhumanists themselves are highly prejudice against handicapped and old people seem to be of minor importance to them.

The first question that comes to my mind is; why do we need this? Maybe there really is something lacking in my intelligence because I cannot see why we need this development. What worries me the most regarding this network is that it does not consist of a bunch of nuts in a basement somewhere. The members are esteemed and well-off individuals whos words carry great weight. For instance one of the chairmen and co-founders is Oxford University philosopher Nick Bostrom.

The reason I present this association to you is that it highlights why it is essential to take moral and ethics into consideration when we discuss how to regulate genetics, pharmacology, nanotechnology and bioengineering in the future. All development starts off well-intentioned on a small scale. But technologies always expand and venture into areas and uses never envisioned at the beginning. I believe that we must put some restrictions on science, and obviously consider morality, ethics and future development in patent law and other regulations, or we may destroy the human nature. I most definitely do not agree with the Transhumanists in that there is no such thing as human nature and that we are essentially "technological creatures".

It will be complicated and hard to draw the line between appropriate and non-acceptable development. Should we allow the use of cloned embryos in stem cell research to e.g. find a treatment for people with spinal cord injuries or use amniotic fluid diagnostics but not allow genetic engineering to allow enhancement of a particular trait? What is acceptable and what is

[135] For more information see http://transhumanism.org/index.php/WTA/perspectives/

not? There are no right or wrong answers but the discussion must be carried on both nationally and internationally. You may think that this discussion goes well beyond the scope of this paper but I see them as highly related issues. The technologies that are being patented in biotechnology today are the foundation for future development and we need to reflect upon the development before it takes us by surprise. Evidently the envisioned technologies are not that far away.

My greatest apprehension is that we will be guided by scared and ignorant politicians. Currently there is a global race to the head of the biotechnological development. In Europe we are afraid that countries like China and the US will overtake the development and that we will be left behind, and the other nations are afraid of the same thing. In their eagerness to be the most competitive knowledge-economy they issue laws and regulations that are motivated by this fear and no one reflects on the greater picture. I believe it is time for us all to stop and think before we proceed.

13. Conclusion

Rather than taking a new angel of approach the governments worldwide rely on old and inappropriate structures for the protection of genetic inventions. The current legal instruments are not suitable for the protection of biotechnology and the traditional requisites cannot be applied. Today there is no distinction between inventions and discoveries, inventive step is basically irrelevant and the utility requirement is largely unessential. Corrections and additions to the regulations that are well suited to their purpose would contribute to new innovations being made and help to distribute these to people worldwide.

Summing up there are many that are opposed to the extensive patenting of genes and other biological building blocks and processes. Some of the most powerful counterarguments to current regulation are based on scientific objections. At the head of the list there is the fact that gene sequences are not really chemical substances but essentially information carriers and have many different functions which make them inappropriate to patent. Furthermore it is not necessary to make any inventive contribution to be granted patent protection today. The systems give rise to patents with extremely broad scopes that do not match the made level of inventive contribution. It is sufficient to merely know one of the functions of a gene to be granted protection for all functions, and even a hypothetical application for a gene sequence originate exclusive privileges to all present and future applications for it. Sometimes patents have such a broad scope that not even the holders are conscious of what is included in their right.

The unfortunate consequences this gives rise to are reinforced by the fact that the knowledge society is dependent on exchange and transaction of information. Genetics and biotech developments are based on cumulative works and numerous wide patents will inevitably block innovation. There are no guaranties that the patent owner will perform any additional research and research will be performed to a lesser extent because later identified functions will be included in the original patent. The industry is reliant on finite resources and the allocation of these. As more and more upstream inventions are being patented companies will be forced to seek licenses from numerous parties and the transaction costs will be significant and the legal tools have to be tuned to better handle these situations

To allow this kind of control over our common genetic heritage will very likely have devastating effects. We will be surrendered to commercial entities' economic considerations and their interest in health, the environment and social benefits. Their profit margin will determine whether necessary research and development will be performed or not. Thus small diseases and those predominantly present in poor countries risk being ignored. The owners can also prevent others from carrying out research and development, or charge fees that will raise the price of future drugs. The habitual argument of the industry, that no research and development would be carried out unless it would be possible to patent the results, do not hold in this discussion. I do not question the protection of applications and treatments, these should without a doubt still be patentable and the derived advantages are motivated for those who have invented something.

A change in the current system is called for. If the patentability requisites were to be applied more strictly and if there was a more rigorous application of the utility requirement, such extensive and problematic patenting as there is today would not be possible. The national courts and maybe even the governments have difficulties to foresee all consequences of legislation and case-law. The decisions on what should be patentable and what should be placed in the public domain should therefore be made by international institutions. These institutions are more likely to have the ability to balance the need for access with the need for economic and commercial incentives.

There are social and economical reasons to why patenting should be restricted as well. Limited access, increased transaction costs and delayed progress costs a great deal of money. It is also in the publics interest to have unlimited access to genetic tests, medical treatments and pharmaceuticals.

The questions that are raised in the ethical discussions must not be disregarded either. Genetics make it possible to change nature, something which has never been possible to do before. Today hereditary factors can be transferred from one organism to another or be adapted to our wishes and this will have unforeseen consequences. We need to consider morality and ethics before we make further advances or we may loose control over the development. The indistinct rules and regulations regarding *ordre public* and morality do not render any help in addressing these complicated issues. Clarifications and distinct demarcations are necessary since these questions of priorities might prove to be more important than the access problem.

I want to point out that I am not against the development and use of biotechnology and genes per se. I believe that research done will help us solve many of the problems and illnesses that we are taken aback by today. What I do oppose is genes being turned into the property of individual entities. I believe that our common genetic heritage must belong to all of mankind and not to any particular entity. It must also be utilized with respect for the equal worth of all humans and it is of utmost importance that we do not change the essence of nature and humanity.

The governments worldwide seem to have become a bit speed-blinded. Both Europe and the US have struggled hard to keep their lead and the law-making seems to have been guided by fear rather than common sense. Legislators and economists seem to think that the stronger protection they create the better it will be. Profits will be maximised and all costs covered. But their reasoning lack insight. It is up to patent law to restrict the scope of upstream patents and to ensure that most upstream research is outside the boundaries of patentability. Considering how important different research paths are for continuous innovation, a system that can distinguish between situations when patenting is appropriate and when it is not need to be devised. The governments also need to act faster and be proactive instead of reactive. Considering the complexity of biotechnological research and the ethical matters this will be a grand task.

ABBREVIATIONS

EPC	European Patent Convention
EPO	European Patent Organisation
NIH	National Institute of Health
OECD	Organisation for Economic Co-operation and Development, an international organisation aimed at helping governments tackle the economic, social and governance challenges of a globalised economy.
R&D	Research and development
SME	Small and Medium size Enterprises
TRIPS	Trade Related Intellectual Property Rights, Agreement regarding trade policy related intellectual property rights, Marrakech 1994
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organisation. The UN's institution for intellectual property.

COVER PHOTOS

Weckenmann (sheep),
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