DEPARTMENT OF LAW AT THE UNIVERSITY OF GOTHEBURG

Master Thesis Fall 2011

30 credits

Reaping more than you sow?

A review of the scope of protection for gene patents and a prediction for its future in light of the ECJ case C-428/08

Sofi Hansson

GÖTEBORGS UNIVERSITET
HANDELSHÖGSKOLAN

Supervisor: Kristoffer Schollin

Examiner: Leif Östling

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Abstract

Patenting genes first developed through US case law in the 1980s. Shortly after Europe followed suit via similar advances granted by the European Patent Office. In the early 1990's the EU started creating a directive aimed to unify how its member states administered biotechnical patents. The aim of the directive was to facilitate trade and to hinder biotechnical industries fleeing Europe in favor of countries with more generous patent legislation. In practice the member state's national laws still remain the basis for gene patents and the directive merely enforced minor adjustments to the member states legislation.

Since the commencement of gene patents a debate over its ethics have raged. Many representatives of different sectors in society are largely opposed to gene patents. This debate has now extended over 30 years and it has become clear that patenting genes is a subject which is far from settled. The Myriad case in the US is a clear demonstration of the steady insubordination of gene patents. Beside the ethical arguments there are also legitimate technical judicial arguments which exclude genes from being patentable on the basis that genes are mere discoveries and thus should not be patentable.

The scope of rights conferred to gene patents is another subject which has voiced a strong debate. The realm of protection for gene patents was directly modeled after the protection assigned to chemical molecules; namely absolute product protection. The absolute product protection allows the patentee to claim infringement on all potential uses of the gene, independent of what industrial application has been stated on the patent application. This is a very broad form of patent which has been criticized for deviate from the patent balance since the scope of protection is not necessarily in relation to the scientific achievement.

When gene patenting was first allowed patent offices were flooded with applications which has now lead to that 20 % of the human genome is patented. Within the US and the EPO case law and guidelines have been presented which limit the patentability of genes. This, along with the presentation of the HGS project, has resulted in a diminished number of patent applications which has thus haltered the patenting rate.

Independent of the raised criteria for patent applications the scope of protection remains broad. The Monsanto case from 2010 does clarify a limitation, namely that the gene has to be functional for an infringement of patent rights to have taken place. It is not enough that the

gene could be purified from the product and inserted into another plant and herein be functional again, the gene has to serve a purpose in the current state for the scope of patent rights to include this situation.

In the aftermath of the Myriad case the US government hired Duke University to produce a report on gene patents and efficiency. This report clarifies that gene patents are not always the most efficient solution to ensure technical developments. To remove gene patents as a whole is not a realistic solution but, as the Duke report indicates, it may be more efficient to segment different types of genes with varying scopes of protection in order to ensure steady advances within biotechnology.

Abbreviations

ACLU	American Civil Liberties Union
DNA	Deoxyribonucleic acid
ECJ	European Court of Justice
EPC	European Patent convention
EPO	European Patent Organization
GATT	General Agreement on Tariffs and Trade
GMO	Genetically Modified Organism
HGP	Human Genome Project
SOU	Swedish government Official Reports (Statens Offentliga Utredningar)
TRIPS	Trade related aspects of intellectual property rights
USPTO	United States Patent and Trademark Officer
WTO	World Trade Organization
US	United States of America

1. Background

"Here between the hither and the farther shore
While time is withdrawn, consider the future
And the past with an equal mind."[1]

1.1 Introduction

In 1953 James Watson and Francis Crick published an article in Nature magazine announcing the discovery of the DNA double helix.[2] In this article the scientists described the DNA structure as having interesting biological properties such as self-replication. What these British scientists had actually discovered was the source of genetic code. Even though they may not have understood the width of their discovery at this stage their announcement was to be the starting point for research all over the world and subsequently the development we see regarding gene patenting today.

The template applied to gene patents was the system of absolute patent protection which was already in use regarding chemical compounds. The possibility of patenting chemical compounds has been available in Sweden since 1978 when Sweden signed the European Patent Convention (EPC).[3] This means that the judicial aspects applied to gene patents are not novel. However, as technology progresses and develops the question of how we limit the scope of protection for gene patents is a problem which is increasingly displaying the short comings of legal developments in relation to its corresponding technology. Gene patents are granted for a twenty year period which is normal for patents; however, in deviation from the norm patents on genes can be awarded for a discovery and not an invention. As long as the gene can be synthesized outside of the human, animal or plant body it is legible for patentability.

The possibility of patenting genes has raised a debate fueled by ethical, social, financial and legal concerns. As research within the biotechnological field is constantly developing so is the debate which surrounds it. Scientists are steadily learning more about the complexities of the DNA helix which consequently alters the playing field for the corresponding gene patents.

[1] Eliot, T.S Eliot Reading The Waste Line, The Four Quartets and Other Poems, The Dry Salvages.
[2] Watson & Crick, Nature 1953 p. 737.
[3] SOU 2008:20 p. 195.

Opinions diverge regarding the scope of protection for gene patents. Some argue that DNA is a part of every person's heritage and that this means that it should be protected from ownership. On the other hand it is argued that DNA is simply a chemical compound which requires patent protection in order to ensure continued research and development within its field of application. Subsequently it is argued that patents on genetic material is vital to ensure further development due to the high costs affiliated with this field of research which requires a right to monopolize ones findings in order to assure continued incentive to invest. There are also many who argue that the patent protection has been taken too far resulting in an elevated level of protection which does not ensure progress but instead inhibits it. As one studies the current debate it becomes inherently clear that this is a highly complex subject that calls for balance between economic incentives and socio-political needs.

The problem which has arisen today is that the scope of rights attached to a gene patent is quite uncertain. While reading the legislation it appears as though the rights attached to genetic patents are limitless but it is in fact within the courts that the limitations are set. However, this is a complex task for the courts who find themselves bound by legislation which has been left intentionally open while bearing the burden of the current debate and the socio-economic implications of the ethics inherently attached to this area.

1.2 Purpose

The purpose of this essay is to examine the legal scope of protection of patents on gene sequences. How has recent development in European case law affected the scope of protection for genetic patents? The essay aims to summarize the legal development of genetic patents as well as predict what the future may hold with regards to the rights conferred by a gene patent.

1.3 Boundaries

The essay will not cover national legislation within the European Union due to the vast amount of time and space that this type of venture would demand. Instead the essay will focus on the directive[4] and exemplify using Swedish legislation. Since Swedish law regarding gene patents is virtually a copy of the directive the Swedish legislation will not be discussed in detail.

[4] 98/44/EC of 6 July 1998 on the legal protection of biotechnical inventions (henceforth called the directive).

This essay will also not cover US legislation. Instead selective US case law will be used in order to illustrate the arguments voiced within US courts as well as arguments heard in media which gives an indication of the attitude towards gene patents.

The essay does not cover the process of licensing or compulsory licensing of gene patents since this is an area which is quite complex and which therefore does not fit within the realms of this essay. Even though the licensing system is a part of the patent system it is not imperative to study licensing in order to fulfill the aim of this essay.

1.4 Theory

In order to fulfill the purpose of this essay I will apply Kaarlo Tuoris theory on critical legal positivism. Tuoris theory is based on the notion that there are several layers of the law and that these layers interact in a way which has influence on the current state and the future of the law. Critical legal positivism does not accept that moral should be something separate from the law, but instead, that law and morals are interconnected.[5] Applied to this essay Tuoris theory allows for an analysis based on the notion that different structures interact with the law thus allowing judicial, financial and moral aspects to be included in the analysis.

Tuori has also coined the concept of the two faces of the law where one face consists of the law as a legal order i.e. norms. The second face of the law is that the law can be approached as a set of social practices which reflect how the law is practiced. The two faces consist of different ways of viewing the law but which are constantly interacting as one cannot exist without the other.[6]

Critical legal positivism describes three levels of the law; the surface structure, legal culture and the deep structure. The laws surface level is most subjected to changes and consists of statues and regulations, case law and documentation from legal sciences.[7] The legal culture changes more slowly and consists of how active lawyers practice the law[8] for example: what is argued and how is this presented.[9] The legal culture is also consists of legal principles which guide interpretations of the law.[10] The deep structure changes very slowly and is based around the notion that there is a common core throughout different legal systems.[11] This

[5] Tuori, Critical Legal Positivism p. 29.
[6] Ibid, p. 121.
[7] Ibid, p. 154.
[8] Ibid, p. 165.
[9] Ibid, p. 167.
[10] Ibid, p. 192.
[11] Ibid, p. 183.

structure is formed by fundamental human rights and broad normative notions.[12] The deep structure is not directly apparent but rather exists on a hidden level where lawyers are not individuals but "*legal subjects of modern society".*[13]

Tuori stresses that all three levels of the law are interconnected in that the surface level of the law sediments down towards the deeper levels.[14] This entails that what is found in the legal culture and deep structure has once been on the surface level and has slowly moved down within the layers.

This essay will apply Tuori's critical legal positivism by aiming to present the different layers of what has effected gene patents developments and its potential future.

1.5 Method

This essay is composed of a compilation of different aspects which have affected and are affecting gene patents. In order to fulfill the aim of the essay it is necessary to sway from the traditional legal method, in order to include all of the necessary angles, which entails that this essay will instead present a socio-political view on gene patents in combination with legislative motives.

Since the biotechnical industry is largely motivated by revenue there is a need to include certain financial aspects in order to present the full aim of the system of gene patents. This will be done by compiling different opinions voiced in media and by formal declarations made by representatives of the biotech industry.

In contrast to the financial aspects it is necessary to present certain human rights and ethical aspects which are fulfilled by studying the past and current debate on access to affordable medicines and ethics on patenting genes. Since gene patents presents an opportunity to discuss sociopolitical values this will also be touched upon.

Gene patents have evolved out of the administrative arena which has largely ruled out the influence of the traditional legislative process. In order to obtain a clear reflection on the development of gene patents case law from the European Patent Organization (EPO), European Court of Justice (ECJ) and US courts will be discussed. These cases will also be compared to each other in order to determine the current scope of protection and the potential future of gene patents.

[12] Ibid, p. 192.
[13] Ibid, p. 185.
[14] Ibid, p. 201.

1.6 Outline

The essay will firstly present a basic background regarding DNA and related concepts. This section of the essay is necessary in order to provide the reader with some fundamental basics which will allow the rest of the essay to be more easily comprehended.

After this the essay focuses on current legislation and related case law. Specifically the essay will discuss the directive on the protection of biotechnical inventions, the European Patent Convention and TRIPS.

The subsequent section then describes the debate which surrounds gene patents. This section will identify the scope of opinions on what should be the rights of the patent holders and in what situations patents for genes should be granted.

Then the Monsanto-case will be discussed where the facts of the case as well as the judge's rulings are presented.

The subsequent sections will focus on exploring the effects of the Monsanto-case as well as predictions for future developments of gene patents. Since Europe is not impermeable to the judicial developments in the US relevant US case law and related developments will also be discussed. The aim of presenting US case law is to provide the reader with a more diversified prediction of the future of gene patents.

2. DNA

In order to help the reader understand the distinction between some basic concepts which are often used while discussing genetics and the background to gene patens this section aims to provide definitions and basic explanations.

2.1 The basics: chromosomes, DNA, genes and genome

All plant and animal cells contain chromosomes in varying numbers; for instance human cells contain 46[15] chromosomes organized into 23 chromosome pairs.[16] Chromosomes are built up of protein and several DNA double helixes.[17]

DNA is can be described as the code for all living organisms and most viruses. DNA takes the shape of a double helix which is basically two strands wound around each other. The strands

[15] *Some individuals can have more or less than 46 chromosomes, for instance people with Down syndrome have 47 chromosomes.*
[16] Calladine et alia, Understanding DNA, p. 4.
[17] Calladine et alia, Understanding DNA, p. 5.

are linear polymers made up of amino acids.[18] The amino acids are called A (adenine), G (guanine), T (thymine) and C (cytosine). These amino acids are arranged in pairs within the DNA double helix[19] and are subsequently the building blocks of the double helix.[20]

A gene is a distinct part of a DNA double helix which carries the code for a distinctive trait. Genes have a very important task in the body; they produce different proteins. These proteins are what make up the body and its functionality. For instance enzymes which catalyze digestion of food is a protein produced by a certain gene which sits within a DNA strand.[21] The human body contains about 30 000 genes.[22]

The genome is a complete set of hereditary information within a full set of chromosomes.[23] In other words; a genome consists of all genes within an individual human, plant or other living organism.

2.2 The Human Genome Project

The human genome project (HGP) which is also known as the Hugo project was an international venture aiming at mapping the entire human genome. The HGP was a collaboration between the US Department of energy, the UKs Wellcome trust, Japan, China, France Germany etc.[24] One of the aims of the project was to allow biotechnical access to the human genome in order to further biological research on human DNA. The project started in 1990 and was completed by 2003.[25] The project was successful in mapping the human genome and the judicial repercussions of the HGP results will be discussed further in chapter 9.

2.3 Genetics in history

Crude attempts at genetic manipulation have been applied for decades. This is a dark area of history where the notion of applying selective sterilization to manipulate the coming population spread through several parts of the world.

[18] King & Stansfield, A Dictionary of genetics, p. 268.
[19] View appendix 1 for an illustration.
[20] Klug & Cummings, Essentials of Genetics, p. 6.
[21] Calladine et alia, Understanding DNA p. 11.
[22] Primrose & Twyman, Genomics: application in human biology p. 19.
[23] King & Stansfield, A Dictionary of genetics, p. 140.
[24] www.ornl.gov/sci/techresources/Human_Genome/home.shtml accessed on 2011-11-22.
[25] Ibid.

In the US in 1907 Indiana passed a law requiring sterilization for genetically inferior individuals, amongst these were *"confirmed criminals, idiots, imbeciles and rapists"*.[26] This law was the result of the lobbying of the eugenics movement. Eugenics was first named by Francis Galton in 1883 and refers to the belief that human characteristics are inherited from parents to the child and thus the eugenics movement believed that the human race could be made stronger and more intelligent by the use of selective breeding. By 1940 a total of 30 states in the US had ratified similar laws which resulted in more than 60 000 involuntary sterilizations until the laws were removed in the 1960's.[27]

The Nazi government in Germany had a similar notion, which is probably not a surprise to the reader. However, the Nazis argued the need for selective sterilization mainly from an economical point of view. In Nazi propagated that the high cost of caring for patients with incurable diseases was the result of poor breeding and which consequently was unwanted. In 1933 the law on preventing hereditarily diseased progeny was passed which enforced involuntary sterilization on bearers of hereditary diseases for example hereditary blindness or deafness as well as alcoholics and individuals living in poverty.[28]

In 1934 and 1941 the Swedish government voted and passed a law which allowed involuntary sterilization on the basis of hereditary, medical or social indications.[29] In 1975 the possibility of forced sterilization was removed but by then 63 000 individuals had been sterilized whereof 50 % involuntarily.[30] Out of the total 63 000 individuals sterilized 93 % were women.[31]

What the wide spread eugenics movement clarifies is that people have been fascinated with the ability of manipulating the human genome for over a century. In short this means that the antecedent of gene patents has a dark history which illustrates how far humans were willing to go in the venture of producing a stronger race.

2.4 Gene patents: areas of application

Major advances within the areas of medicine and agriculture have been made possible by the use of biotechnical inventions. In an effort to supply the reader with an idea of the areas of

[26] www.iupui.edu/~eugenics/ accessed on 2011-09-26.
[27] Allen, Technology Review 1996, p. 23-31.
[28] Ibid.
[29] SOU 2000:20 p. 15.
[30] Ibid, p. 16.
[31] Ibid, p. 16-17.

application for biotechnical inventions this section of the essay will introduce the most common uses.

2.4.1 Agriculture

By using hybridization to perform genetic manipulations plants have been improved in four main ways:

1. Increased yields.
2. More resistant to pests and diseases.
3. Combination of traits from different species.
4. Increased levels of a certain desirable quality.[32]

By genetic research scientists have reached great results regarding several different kinds of plant. For instance in the US it is estimated that genetic enhancement has increased the crop yield by a threefold. As is mentioned above it is also possible to produce crops with specific desirable qualities which has been done in, for instance, Mexico where scientists have been able to produce a type of corn with elevated levels of protein.[33] The result of the research can be limitless, imagine, for instance, a plant which can grow on minimal water while yielding crops with maximum levels of nutrients. This type of invention could be life saving in countries struck by famine and drought.

By selective breeding scientists have also produced chickens which grow faster and lay more eggs as well as cows and pigs that grow faster and bigger.[34] One example which has appeared frequently in media is the cow breed called Belgian Blue. While developing the breed Belgian Blue, which displays double the muscle mass of normal cows, an intricate method of gene mapping and selective breeding was used.[35]

2.4.2 Medicine

Presumably medical development is the most common association to biotechnical inventions. While probably being the most controversial area of research it is also an area which many people depend upon.

To name one; the production of human growth hormones was a result of a genetic patent which was held by an American company and a method for reproduction produced by the Swedish pharmaceutical company called Kabi-Vitrum. Kabi-Vitrum purchased the rights to

[32] Klug & Cummings, Essentials of Genetics, p. 11.
[33] Ibid.
[34] Ibid.
[35] Grobet et alia, Nature Genetics 1997**,** p. 71-74.

the gene patent for growth hormones from the Americans and inserted the gene into E-coli[36] bacteria.[37] The bacteria then started to produce large quantities of the hormone and the protein could be purified from the bacteria. This bacterium becomes a gene manipulated organism once the gene is inserted into it. This process is applied to produce medicines for several different diseases for instance diabetes, hemophilia, proteins which dissolve thromboses.

Another area of great promise is that of gene therapy. Today it is possible to insert modified genes into human cells in order to replace a damaged gene which is causing a defect.[38] The long term aim of gene therapy is to permanently treat diseases where currently existing medicines can alleviate symptoms but not cure the patient. For instance the method could be used to replace genes which make the carrier more prone to cancer with healthy genes. Gene therapy is in its early stages and is still being tested but may develop into a theoretically limitless tool to treat genetic diseases.[39] There are two types of gene therapy; somatic and zygotic. There is an important distinction to be made regarding gene therapy where somatic gene therapy results in the replacing of a gene in that specific individual which entails that this individual cannot pass the gene on to its offspring.[40] Human zygotic therapy is a method where certain genes are replaced by other genes in such a manner that they will be inherited by the carrier's offspring.[41] This means that diseases like Huntington's disease, which is usually detected later on in a person's life, could then potentially be eradicated as the genes coding for Huntington's could be replaced by a healthy gene. Zygotic gene therapy has, for many years, been successfully used by scientists in tests on animals.[42]

These are only a few examples of the areas of biotechnology which have resulted in progress in medical research. Since the areas of application for biotechnical inventions is so vast it's safe to say that it generates a very large amount of money and is of great importance for the sustenance of many people.

3. EPO & EPC

Before the directive was implemented in 1998 European gene patents have been distributed via the EPO. The development of admissibility of gene patents within Europe was instigated

[36] *A bacteria naturally found in the intestines of humans and animals.*
[37] Brändén, Genteknik, kloning och stamceller, p. 20-21.
[38] Primrose & Twyman, Genomics: Applications in Human biology p. 178 f.
[39] Ibid, p. 14-15.
[40] www.brown.edu/Courses/BI0032/gentherp/IIAB.htm accessed on 2011-12-17.
[41] www.genteknik.nu/index.asp?id=389&typ=print accessed on 2011-11-29.
[42] Brändén, Genteknik, kloning och stamceller p. 79.

by the application of the Harvard Oncomouse patent as early as 1984.[43] In order to understand the relationship between the legislation constructed by the European Union and the European Patent Office this section aims to clarify and decipher the importance of the EPO and its relation to the legislation within the European Union.

3.1 What are the EPO and the EPC?

The EPO is an intergovernmental organization which was constructed in 1977.[44] The EPC was signed in Munich in 1973 and is the legal foundation of the EPO. The EPO currently holds 38 members, whereof Sweden joined in 1978.[45]

The EPO grant patents which are upheld throughout their 38 member states. In 2010 the EPO granted 136 700 patents whereof 2194 were in biotechnology.[46]

3.2 The relationship between the EPC and the directive

In order to avoid clashed between the EPC and the directive certain provisions were met to secure that the compatibility of the two documents. Within the Implementation regulations[47] of the EPC rule 26 clarifies that the EPC should be interpreted within the light of the directive. The directive also refers to the EPC in recital 15 where it is stated that the EPCs provisions should be regarded while implementing the directive. It is therefore clear that there the two documents are interconnected which indicates that there is a desire to unify the two systems to avoid incompatibility.

3.3 Opposing a granted European patent.

If the decision of the EPO to grant a patent is believed to be incorrect a third party may request that the EPO re-examine the application.[48] The third party must file an opposition with the EPO within nine months of the grant of the patent.[49] The opposition must be on the grounds that[50]:

- The patented subject is not patentable under article 52 to 57 i.e. the subject is not new, inventive or is not industrially applicable.

[43] Patent number EP0169672 & www.epo.org/news-issues/issues/biotechnology.html accessed on 2011-12-01.
[44] www.epo.org/about-us/organisation.html accessed on 2011-09-29.
[45] SOU 2006:70 p. 106.
[46] www.epo.org/about-us/statistics/granted-patents.html accessed on 2011-09-29.
[47] *The full name is: Implementing regulations to the on the grant of European patents as last amended by the decision of the Administrative Council of the European Patent Organization of 26 October 2010.*
[48] EPC article 99.
[49] Ibid.
[50] EPC article 100.

- The invention is not disclosed in enough detail.
- The patented matter extends beyond the content of the application.

The review of the patent application is an administrative process which is performed by opposition divisions of the EPO.

The objection is firstly administered by an Opposition Division consisting of three technically qualified examiners whereof at least two should not have been involved in the grant process.[51]

If the decision of the opposition division is unsatisfactory to any party they may file an appeal which will then be administered by the technical boards of appeal[52] within two months[53] of the decision of the opposition division. There are currently 27 Technical Boards of Appeal in addition to the Large Board of Appeal, the Enlarged board of appeal, and the Disciplinary Board of Appeal.[54]

4. Directive on legal patentability of biotechnical inventions

4.1 Background and legislative motive

The directive was preceded by the American case *Diamond v Chakrabarty*[55] from 1980 where it was concluded that a live microbiological organism was patentable under US law. In an effort to harmonize European law and counter-act biotechnical companies fleeing Europe to relocate in countries with more generous patent legislation[56], the EU followed Americas lead and approved the directive in 1998.

The road towards the directive was not, however, straight. After seven years of revised drafts of a biotechnology directive the European Commission tried to convince the parliament to adopt a version of the directive in 1994. The ethical discussions rose high as some argued that the moral debate had been taken into account adequately while outlining the directive whilst others, mainly the Green Party, disagreed. For instance, Linda Bullard who was a staff member of the Green Party stated that *"We feel that Parliament, having voted previously against patents on parts of the human body - including genes- under any circumstances, is morally obliged to reject this compromise*".[57] The 1994 version of the directive was never

[51] EPC article 19(2).
[52] EPC article 107.
[53] EPC article 108.
[54] www.epo.org/about-us/boards-of-appeal.html accessed on 2011-12-06.
[55] Case number 447 U.S. 303.
[56] Scalise & Nugent, Fordham International Law Journal, 1992, p. 991f.
[57] Dickson I, Nature 1995, p. 550.

enforced due to lack of support in the European Parliament. On the rejection of the directive Peter Doyle who was the executive director Zeneca Ltd[58] stated *"...it is a very negative signal to the world at large about the worthwhileness of investing in biotechnology in Europe."*[59] It became clear that there was a large gap between the will of some of the members of European Parliament and the biotech industry. The setback for European gene patents was not to be long lived; in 1998 the directive was reconsidered in the Parliament and this time it was approved.

The difference between the legislative development in the US and Europe is that ethical aspects had to be included in the discussion on the directive. The basis for the ethical discussed was that the European Patent Convention states that inventions which are contrary to *"ordre public or morality"*[60]cannot be patented. The effect of this prohibition was that ethics were a natural brake in the distinction of the directive where it was not a legislative based factor in the development of US policy.[61] Since the directive and the EPC are interconnected this resulted in a more long lived ethical debate with a heightened legitimacy.

After several years of debates throughout the member states the directive was finally accepted in 1998.[62] Even though the debate had been fueled by widely diversifying opinions it was made clear that the aim of the directive was to unify the different legislations within Europe in order to avoid barriers to trade.[63] It had also been noted that the developments within genetic patents were basically demanding protection for their discoveries in order to allow these industries to grow.[64] Research and development of new products related to genetic sequences was notably very expensive and in order to further stimulate these businesses one of the aims was to give them further encouragement by allowing genetic patents.[65]

4.2 Claim against the directive

Besides the discussion concerning ethics on allowing patents on genes, mentioned above, there was turbulence within the European Union while voting on the future of the directive. Sweden, along with another eleven member states voted to implement the directive while the

[58] *A British biotechnical company which fused with the Swedish biotechnical company Astra in 1999 to create AstraZeneca.*
[59] Dickson II, Nature1995, p. 103.
[60] EPC article 53.
[61] Kevles & Berkowitz, Brooklyn Law Review 2001 p. 243.
[62] Scalise & Nugent, Fordham International Law Journal 1992, p. 992.
[63] Directive 98/44/EC preamble article 5.
[64] Ibid, article 1.
[65] Ibid, preamble article 2.

Netherlands voted against the directive and Italy and Belgium chose not to vote.[66] After the directive was passed the Netherlands filed a claim against the European Parliament[67] which was supported by Italy and Norway.

The claim presented six separate pleas by the Netherlands; amongst them were breaches against the principle of subsidiarity, breach of the principle of legal certainty, breach of the respect for fundamental respect for human dignity, breach of obligations under international law etc. However, all pleas were declined in court leading to the courts favoring the side of the European Parliament and the subsequent adaptation of the directive. The courts clearly expressed that they favor the side of the parliament and that the directive is clear enough not to interfere with human dignity.[68]

Even though the Netherlands claims were not favored by the courts this case clearly illustrates how questioned the directive and patents on genes were before the implementation of the directive. The case and the attitudes towards patenting genes will certainly have effect in the development of gene patents since the directive is very vague and does not specific limitations which will then leave individual courts to decide the scope of this form of patents. The essay will discuss this topic further under chapter 9.

4.3 Invention vs. Discovery

As a principal rule an object viable for patentability has to be an invention and could not constitute a mere discovery. This was the historical point of view but as the directive was implemented it became clear that those rules would have to be adjusted with regards to gene patents. Patentable gene sequences can occur naturally which means that the patentable subject is not an invention in the common use of the word but merely a successful development in science where a gene strand has been extracted in order to be utilized for a purpose.

Instead of claiming that discoveries should be allowed to be patented the directive states that a genetic strand which can be synthesized outside of its natural habitat (for example a human, plant or animal body) should be considered an invention.[69] By this method the parliament doesn't proceed to expand the realm of patentability to include discoveries instead it chooses to re-define the concept of invention within biotechnology. Simply put the commonly used

[66] Proposition 2003/04:55 p. 39.
[67] The Court of Justice of the European Union C-377/98.
[68] Ibid, point. 77.
[69] 98/44/EC of 6 July 1998 on the legal protection of biotechnical inventions article 3.2.

definition of an invention does not equal the legal definition.[70] By using this method the directive does not open up the flood gates for masses of new patent applications regarding discoveries it merely shifts the concept of an invention to fit the purpose. The directive simply put expands the concept of an invention in order to include gene sequences.

4.3.1 The Relaxin-case

The reader might find it useful to know that this concept of expanding the word invention was not novel to European patents when the directive was adopted in 1998. The EPO had granted a patent on the human gene which codes for the protein Relaxin in 1995.[71] This entails that patents had already been awarded discovered and synthesized gene strands prior to the implementation of the directive.

It is important to note that within the EPC a similar legislative standpoint is enforced regarding discoveries where article 52.2.a excludes discoveries from patentability. This verdict can be considered to have laid the ground work for a more extensive interpretation of the word invention and a more lenient attitude towards gene patents.

4.4 Criteria for patentability

The directive fixes a set of rules for when gene sequences can be eligible for patenting. Within this directive the parliament has chosen to continue using the previously ascertained criteria for patentability. These elements will be discussed here in order to provide the reader with the frame work for the distinction of when a gene can be patented or not.

4.4.1 Industrial Applicability

The aim of the industrial applicability criteria is to limit patent applications to those which actually have a discovered use. Regarding gene sequences the directive clearly states that a patent cannot be granted if the patentee does not know the function of the patent.[72] This means that it is not enough to simply identify a gene in order to be granted a patent; the applicant needs to be aware of what the gene codes for and subsequently how this gene could be utilized.

The directive does not clearly define the element industrial application; however the EPC does provide a definition and since the directive states that the two documents are

[70] Pamp, Intellectual property in Science, p 215.
[71] EPO case number T 0272/95.
[72] 98/44/EC of 6 July 1998 on the legal protection of biotechnical inventions recital 23.

interlinked[73] the definition from the EPC is presumably applicable on the directive. The demand for susceptibility for industrial application[74] invokes that the patentable subject can be used in any industry, including agriculture.[75] In the case of gene patents these are mainly medical and agricultural industries. It's important to note that there is no need for the applicant to prove the actual use of the gene sequence, it is sufficient to express a possible use.[76] However, it is clearly stated within the directive that the industrial application must be stated on the patent application.[77]

The directive chooses to limit the possibility of patenting gene sequences to the cases when the applicant can show an industrial application but at the same time the definition of the element industrial application is very wide. By extension it seems that the European parliament has chosen to leave the definitions of industrial applicability to the courts since there are no explicit limitations provided within the directive. In spite of the seemingly diaphanous requirement of industrial application for a gene the two subsequent sections will elaborate on the limitations of the criteria.

4.4.1.1 BDP Phosphatase - case

In the case *BDP Phosphatase/MAX PLANCK*[78] the Max Planck institute had applied for a patent for BDP1-polypepti which was thought to be able to neutralize another protein in the body which was believed to increase the risk of developing colon cancer. In the patent application the Max Planck institute had submitted that BDP1 could be used in pharmaceuticals. The EPO decided that the patent could not be upheld since the applicant had not presented how the patent was to be used specifically. The EPO stressed that there had to be a difference between what could be patented and what was merely the result of interesting research.[79] The EPO further expresses that it is not valid to patent genes as a method of monopolizing potentially interesting research areas.[80]

The case clarifies that a further level of detail regarding the genes industrial applicability is needed in order for a patent to be issued.

[73] Ibid recital 15.
[74] Ibid, article 3.
[75] EPC article 57.
[76] Seville, EU Intellectual Property law and Policy, p. 117.
[77] Directive article 5.3.
[78] EPO Case Number T 0870/04.
[79] EPO Case Number T 0870/04 Reasons for the decision point 6.
[80] Ibid, Reasons for the decisions point 22.

4.4.1.2 Bioinformatics & the ICOS case

Bioinformatics is the interdisciplinary study of biology and information technology[81]. By using databases containing information on known DNA sequences and their functions it is possible to calculate the probable function of an isolated strand of DNA. This tool is immensely useful to researchers as it gives them a reasonably accurate prediction of the function of a gene. However, it is important to note that the database can only supply a predicted function; the prediction is not a guarantee of the correct function.[82] Because patent applications are often submitted early in the research process this has meant that the predicted function has repeatedly been used in applications. The issue of patent application with a speculative industrial application was addressed by the EPO in the ICOS-case.

ICOS was one of the largest biotechnical companies in the US until 2007 when it was sold to Eli Lilly.[83] ICOS had applied for and been granted a European patent[84] for a DNA sequence which they claimed could be used as a receptor. Two separate biotechnical companies filed an appeal which was administered by the opposition division who passed judgment in 2001.[85] The case examines the definition of industrial applicability and when a DNA sequence is to be regarded as reaching the standards set by the EPC. ICOS argued that EPC article 57, which states the need for an industrial application of a patentable subject, is fulfilled if the product can be used in any industry.[86] As mentioned earlier ICOS argued that the DNA sequence could be used as a receptor within the area of immunology which they had stated on their patent application. However, the opposition division found this argument lacking stating that:

"*In view of the requirement of industrial application as set in Article 57 EPC in conjunction with Rule 23b-23e EPC[87], the invention cannot be acknowledged as industrially applicable because industrial applications are not disclosed in the patent application*"[88]

This citation stresses that article 57 of the EPC, which merely states that industrial application is fulfilled if the invention can be used in industry, should be interpreted alongside with current rule 26-29 which state that the directive can be used as a basis for interpretation. The courts state that the mere indication of a use cannot be acknowledged as fulfilling the

[81] Fulekar, Bioinformatics: application in life and environmental science, p. 1f.
[82] Schertenleib, European Intellectual Property Review 2003 p. 2.
[83] www.investing.businessweek.com/research/stocks/private/snapshot.asp?privcapId=192427 accessed on 2011-11-23.
[84] European Patent Number 0 630 40.
[85] Decision of the opposition division, 20 June 2001, O.J.EPO 2002 p. 293, ICOS Corporation (cit. ICOS-case).
[86] Ibid point 8 ii p. 303, see note 81.
[87] *As of the update 2010 article 23b-23e are now rule 26-29 EPC.*
[88] Decision of the opposition division, 20 June 2001, O.J.EPO 2002 p. 293, ICOS point p 9 p. 304.

industrial application criteria. The Opposition Division further stated: *"Thus the potential uses disclosed in the application are speculative, i.e. not specific, substantial and credible as such are not considered industrial applications".*[89] The Opposition Division hereby states that the patent application requires further specification than what ICOS had submitted to fulfill the industrial application criteria. Within the ICOS patent application was a disclosure of an area of use for the gene; however, the application was not considered specific enough which lead to the Opposition Division revoking the patent. This case can be seen as a turning point for the EPO where they now apply elevated standards regarding industrial applicability and thus require further detailed use from the patentee. Even though the demand for an industrial application within article 57 is very loosely stated this case displays a heightened interpretation of the wording of article 57 consequently raising the bar for the criteria of industrial application.

Since this case was not appealed the precedent can be discussed, however the demand for a more specific level of industrial application has been upheld since the judgment was passed in 2001. This will be discussed further in chapter 9.

4.4.2 Novelty

The novelty requirement in article 3.1 of the directive means that a gene cannot be patented if it is previously known to the public. The public does not have to entail a large collection of people, it is enough for the gene to be known somewhere in the world to a certain group of people for the patent application to fall short of acceptance. The patented subject does not have to be in industrial use, it is enough that it is known by word of mouth or by any documentation.[90]

One of the complexities which arise while discussing genet patents is that it could be argued that all genes are "known" to the public as they exist naturally in humans, plants, animals or other organisms. However, it has been stated that the previous existence of a gene does not make it public knowledge. In the previously mentioned EPO case *Relaxin* the courts announce that since the gene is not mentioned in any previous documentation it is acknowledged as being new.[91] By other words the court's interpretation means that a gene has to be documented previously in order for it to fall short of the novelty criterion, it is not enough that it merely exists.

[89] Ibid point 9i p. 304.
[90] EPC art 54.2.
[91] EPO Case T 0272/95 Reasons for the decision point 10.

4.4.2.1 Translational inhibition-case

This case tests the boundaries of when an invention can be considered known to the public and fall short of the novelty criteria.

In the case *Translational inhibition/RESEARCH FOUNDATION*[92] a patent application was filed with the EPO for a gene which consisted of three vital parts. Other biotechnical companies argued that this gene had been presented to the public both via an article and at a seminar which was attended by 100 people. However, in the article only one part of the gene was presented and the EPO found that the presentation could only be considered public if the patentable material was presented clear and unmistakable.[93] Because the article was missing vital information the novelty criteria was considered to be upheld.

The gene was also presented at a seminar which was attended by 100 people. The EPO held that because the attendants were obliged to sign non-disclosure agreements the presentation of the invention could not be considered public knowledge.[94]

4.4.3 Inventive step

The final criterion enforced under the directive is that the patent application must contain an inventive step. This term, along with the other elements of patentability, is not defined by the directive. However, parallels can be drawn to the definition which is supplied in article 56 of the EPC. Herein an inventive step is defined negatively as something which is not obvious to someone who is skilled in the particular art. Someone skilled in the art is a person who has access to the latest literature on the subject and who has the ability to perform experiments.[95]

By requiring an inventive step to administer a gene patent the legislator aims to secure that patents should solely be awarded to those inventions which can be considered an inventive feat.[96] In an attempt to crystallize the content of the element inventive step the EPO has defined it as *"a step from the technical problem to its solution."*[97] The aim appears to be to reject patent applications which risk blocking the development of research.

[92] EPO Case T 0838/97.
[93] Ibid, Reasons for the decision point 9.
[94] Ibid, Reasons for the decision point 7.
[95] SOU 2008:20 p. 152.
[96] Ibid, p. 153.
[97] EPO case ICI/Containers T 0026/81 Reasons for the decision point 9.

In practice this criteria seems to be quite difficult to anticipate for applicants which has resulted in that over half of the appeals made to the EPO are in regards to a lacking inventive step.[98]

4.5 Absolute product protection

Absolute product protection is basically a patent where the patent rights are not bound by the specifications on the patent application.[99]

Before gene patents were admissible absolute product protection was awarded patents on chemical compounds. This extensive type of protection came firstly from the US where it was enforced after world war two. In Europe this principle was legislated in 1950 and it was implemented in Sweden in 1978.[100] The principle is not crystallized directly within the EPC or the directive but can be seen through studying case law and indirect effects of article 6 of the directive.

4.5.1 Absolute product protection on gene patents

Article 6 of the directive establishes that the applicant needs to state the industrial application of the gene they wish to patent. This article has been translated into the Swedish patent act 8 §. It is misleading to assume that the demand for industrial application regarding gene patents limits the patent to that particular the application. In fact, this is not the case; the demand for industrial application is a mean of hindering applications from coming in before the function of the gene has been determined.[101] The nature of absolute product patent is that once the patentee has gained a patent for a gene the rights conferred by the patent are not limited by the industrial application of the patent application but extends to all areas of use for that gene. In other words the reason that the gene patent demands an industrial application is only to ensure that the patent office's aren't flooded with applications for which there is a lacking practical use since this risks creating a dead-lock in research development. In the previously mentioned case *BDPA Phosphatase/MAX PLANCK* the EPO's board of appeal, on the issue of lacking industrial application, states: *"The purpose of granting a patent is not to reserve an unexplored field of research for an applicant".*[102] It is also important to note that a gene can code for several different proteins which means that the industrial application stated on a patent application can be one of many functions which that gene codes for.

[98] SOU 2008:20 p. 153.
[99] SOU 2006:70 p. 104.
[100] Ibid, p. 105-106.
[101] Ibid, p. 111.
[102] EPO case T 870/04 Reasons for decision point 21.

The question which arises is if absolute product patent for a gene then entails that that the patent holder can monopolize that particular gene? This is not the case. If one actor has been awarded a patent for a gene and another actor wishes to patent that particular gene but for another industrial application this is possible.[103] The situation would then be that the owner of the first patent is the primary patent holder while the second actor would have to get a license from the first actor holding the primary gene patent in order to be able to utilize the gene in a product.[104] If the holder of the patent does not wish to comply and award a license it is possible to have a compulsory license expedited[105], but this is not explored further within the scope of this essay.

Assigning absolute product protection has been widely discussed. Some find it absolutely natural to award absolute product protection to genes arguing that the process is so similar to that of discovering chemical compounds that it is only natural to award an elevated level of protection to genes as well.[106] This is a similar point of view as the EPO took in the above mentioned *Relaxin-case* where genes were concluded to be chemical entities. The debate of if the absolute product protection should be implemented throughout Europe has been very diverse and long. Within the Swedish Official Reports[107] the Swedish government carefully followed up the implementation of absolute product protection and stated the advantages and disadvantages of such a vast protection:

Advantages:

1. A patent limited to the industrial applicability is difficult to define which might lead to an increase in patent infringement processes.

2. Research corporations may chose not to perform research as they find the level of protection too limited.

3. The problem of *royalty stacking*[108] may increase resulting in a decreased incentive to invest in research.

4. Absolute product protection results in a higher incentive to invest in research.

Disadvantages:

[103] SOU 2006:70 p. 18f.
[104] Domeij, Patenträtt p. 51f.
[105] See for example chapter 6 of the Swedish Patent Act.
[106] Straus, International review of intellectual property and competition law 1995 p. 926.
[107] SOU 2006:70 &SOU 2008:20.
[108] *Arises when a company has to award all the other patent owners licensing fees in order to sell their product.*

1. Absolute product protection means allowing a greater level of protection then the patentee's discovery may be worth.[109]

In total the committee of the Swedish preparatory works examined the effects of absolute product protection found that the advantages played a larger practical role and thus this form of patent protection for genes is still applied. From examining the stated advantages it becomes clear that the committee has largely focused on practical administrative factors of absolute product protection and has thus reduced the importance of obtaining a balanced patent system.

Notably not all members of the EU apply absolute product protection within their national legislation. Germany, France, Italy, Luxembourg and Switzerland have chosen to assign a more restrictive scope of protection on gene patents.[110] One of the aims of the directive was to unify the EUs member states legislation with regards to gene patents and the varying applications of absolute product protection means that this goal has not been met fully.

5. TRIPS

Sweden has been a member of the European Union since 1995 and with this membership followed an obligation to also become a member of the World Trade Organization[111] (WTO). Beside the separate member states of the EU requiring membership in the WTO the EU is also a member[112] thus is important to note the influence that WTO law can have on the legislation of the EU and its member states.

5.1 What is TRIPS

Trade related aspects on intellectual property rights (TRIPS) is a legal WTO document. The document consists of a legal framework recognizing intellectual property rights which are to be upheld by the WTO's member states.

5.2 The politics behind TRIPS

Even though the original GATT[113] document signed in 1947[114] established some basic positive rights for IP it would take until the Uruguay Round which spanned from 1986-

[109] SOU 2008:20 p. 207-208.
[110] Ibid, p. 197.
[111] www.wto.org/english/thewto_e/countries_e/sweden_e.htm accessed 2011-09-30.
[112] Ibid.
[113] *General Agreement on Tariffs and Trade, a legal document within the WTO framework.*
[114] Van Den Bossche, The law and policy of the world trade organization, p. 742.

1994[115] to construct TRIPS. Separating and expanding the IP rights was largely a result of political discussions. It was argued that free trade would be largely hindered by some member states lacking IP rights rendering the removal of barriers to trade basically meaningless.[116] The reason for this argument was the fear that a product could be successfully exported into a nation where the trademark and product could be legally copied and distributed leaving the incentive to trade between the parties greatly diminished.[117]

The marriage of trade and intellectual property rights through TRIPS has been greatly criticized by those who find that this systematically excludes developing countries from developing while allowing developed countries to remain thriving.[118] One argument put forth is that TRIPS and the WTO's effect is that the developing countries are now begrudged the possibilities which allowed today's developed countries to develop.[119] The enforcement of TRIPS was largely a result of the US and other industrialized countries lobbying in the WTO. Herein the industrialized countries argued that the developing countries were constricting the trade opportunities for industrialized countries by production and sale of counterfeiting products.[120] The basic notion seems to be that the developed world forced the less developed member states to agree to TRIPS which resulted in a situation where the developing world control intellectual property rights and thus hinder developing countries from expanding.[121]

5.3 Relationship between TRIPS and European Law

Membership in WTO binds its members to uphold the TRIPS document. Notably in *Merck Genéricos v Merck and Co* the ECJ expressed that it was up to the individual member states to chose if they wished to give the TRIPS agreement direct effect or not.[122] The TRIPS agreement has not yet been given direct effect within the European Union but the ECJ's case law shows a clear striving to act in accordance with the TRIPS agreement.

In *Dior and Others* the courts proceeded to clarify that the when community legislation is applicable these provisions should be interpreted with TRIPS in mind.[123] It's important to note that even though TRIPS does not have direct effect the agreement needs to be kept in

[115] www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPs accessed on 2011-10-19.
[116] Van Den Bossche, The law and policy of the world trade organization, p. 743.
[117] Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods Protocol for Meeting of 25th of March 1987 p. 4.
[118] Meardon, History of Political Economy, 1995 p. 145-146.
[119] Chang, Kicking Away the Ladder, p. 128.
[120] Correa, Intellectual Property Rights, the WTO and developing countries, p. 3-5.
[121] Ibid.
[122] ECJ case number C-431/05 paragraphs 47-48.
[123] ECJ joint cases C-300/98 and C-392/98 paragraph 49.

mind while discussing European law since it, according to above mentioned case law, can influence the interpretation of provisions of European intellectual property law.

6. Opinions on gene patents

Since patenting genes is a highly controversial subject it has fired an ethical debate which has been in progress for decades. The debate descants the question of legibility of gene patents as a concept as well as the different views on appropriate limits on the scope of rights attached to genetic patents.

In a decision from 1998 the EPOs board of appeal states:

"In such a situation, a proper balance must be found between, on the one hand, the actual technical contribution to the state of the art by the invention disclosed in said patent or patent application, if any, and, on the other hand, the manner of claiming so that, if patent protection is granted, its scope is fair and adequate."[124]

Patenting genes is a very complex issue which does not appear to encompass correct answers merely adequate compromises in an effort to reach a balanced system. This chapter aims to present varying views on the span of rights connected to gene patents in order to allow the reader to gain an understanding of the debate.

6.1 Arguments supporting gene patents

It is apparent that there are many strong forces who have acted towards gaining the right to patent genetic materials. If the contrary was instead a fact then we probably would not be able to patent genetic materials the way which is possible today. It has already been mentioned that the ability to patent genes originated in the US in 1980 and that this development lead to a debate in Europe which aimed to allow European patents within the same arena. One of the aims of expanding the realm of patents to include genetic material was to allow European companies to compete on the same level as corporations based in the US. This section of the essay will present the arguments for allowing gene patents.

6.1.1 Encourages research

One of the most founded arguments which re-occur in gene patent discussions concerns financial considerations. Since gene patents are granted within the US it is almost impossible to disallow the same level of protection within Europe. Hampus Rystedt, who was a manager

[124] EPO case T 0694/92 Reason for decision point 3.

at the Swedish patent and registration office, argued that if we had not enforced gene patents then this would inevitably entail that research would not be performed by private research foundations and this would mean that all research would instead be dependent upon government funding.[125] The reason for his argument is quite simple, private research foundations would lack financial incentive to develop medicines and perform research. Genetic research is very costly and private corporations would require security in the form of a patent protection in order to motivate them to invest in this type of research.

It should also be noted that the line of argument which aims to keep researchers motivated has also been presented in Australia where a change in the law which threatens to rule out gene patents have lead to learned individuals expressing their fears that this could lead to research companies fleeing the country and thus stiffening scientific developments within genetics.[126]

As a comparison it should be noted that in the US a drug is estimated to have cost $800 million and have taken 12-15 years before reaching the market.[127] Even though not all gene patents are used to produce pharmaceuticals this comparison might give the reader an idea of the vast amount of money which is consumed during medical research and the need for patent protection as an incentive to invest such vast amounts of money.

6.1.2 A gene patent is not owning life

Harvard Professor and CEO of the company Human Genome Science, William A. Haseltine, introduces a scientific and ethical argument for gene patents where he wishes to clarify what lies behind a gene. Haseltine argues that a common misunderstanding lies at the core of the arguments posed by those who are against gene patents where gene patents have wrongfully been assumed to allow individual companies to own the entire human genome.[128] This is not the case according to Haseltine, instead the genes which are patentable are single artificially synthesized genes which are used to create new medicines and develop pharmaceutical research.[129] The point which Haseltine tries to clarify is that there appears to be an ethical confusion in the current debate where genes are assumed to be interchangeable with life. Haseltine tries to clarify this miscomprehension by expressing that a patentable gene is something completely separated from the human body and that this by extension means that

[125] Rystedt, Svenska Dagbladet, 2002.
[126] Rose, The Sydney morning Herald, 2009.
[127] www.pbs.org/wgbh/pages/frontline/shows/other/interviews/powell.html accessed on 2011-10-24
[128] Haseltine, Technology Review, September/October 2000 p. 59.
[129] Ibid.

gene patents do not pose a threat, instead it will stimulate research which will be of great benefit to many.

David B. Resnik, a specialist in bioethics at the National Institute of Environmental Health Science in the US, follows a similar line of argument where he argues that owning the entire genome might pose as a risk to human dignity but that owning specific genes does not. He also argues that ownership of the entire human genome is something highly unlikely and thus does not pose as an actual threat to humanity.[130] Since the unveiling of the results of the HGS project owning the entire human genome is not a judicial possibility and by Resnik's logic this entails that gene patents should be admissible as they do not constitute a threat to humans.

6.1.3 Patents do not inhibit scientific development

One concern which has surfaced is that allowing gene patents will actually result in a less effective and decelerated research capacity. The logic behind this concern is that when gene patents are awarded to single pharmaceutical companies the remaining research companies will be locked out of using that particular gene thus making it impossible for other companies to continue researching on that particular gene. Timothy Caulfield, the Canadian Research Chair in health and law policy, states that there is actually no evidence supporting that gene patents would lull the advances of research.[131] Notably about 20 % of the human genome is patented[132] but in a US survey from 2005 the national academy for science found that only 1 % of projects were delayed more than one month due to complications with patents.[133] This result may appear to present a situation where gene patents are not in fact a problem for further research but interpreting the survey's results may be misleading due to that research companies may merely chose not to continue their projects once they have found that the gene is patented. Since the report merely presents delays and does not actually deal with cancelled or not pursued projects this report in itself may not actually paint a fair picture. However, in 2007 the American associate for the advancement of science found there to be *"very little evidence"* for that IP protection should impede scientific research.[134] In all Caulfield argues that it is not logical to assume that gene patents lock out potential researchers, however, depending on how the results are interpreted, this point of view may not be completely fair.

[130] Resnik, The journal of law medicine and ethics,2001 p. 163.
[131] Caulfield, Science Progress, 2009.
[132] Ibid.
[133] www2.druid.dk/conferences/viewpaper.php?id=776&cf=8 accessed on 2011-12-15 p. 2.
[134] sippi.aaas.org/Pubs/SIPPI_Four_Country_Report.pdf accessed on 2011-10-24 p. 12f.

6.2 Arguments against gene patents

Since the topic of gene patents was introduced it has been a very controversial issue. There are many different groups of people who fear the repercussions of the judicial change which legalizing gene patents entails. This section of the essay will focus on the arguments posed for limiting or removing the ability to patent genes.

6.2.1 No one can claim ownership to the human body

One of the most fundamental arguments which has surfaced in this debate concerns ownership of the human body. It seems as though one of the greater fears attached to gene patents is in regards to the fact that a company could come into possession of a building block of people's bodies.

One of the instances which argue against gene patents on the grounds that it should not be possible to own a part of the human body is the Swedish National Council of Medical Ethics (henceforth called the council). The council sent their opinion on the directive to the Swedish department of Justice in 2002 and herein they explain that the possibility of claiming ownership of the human body should not be possible.[135] One of the fears that the council expresses is that the patentability of genes risks limiting research and hindering health care. The Council express great opposition to the implementation of the directive on the ground that monopolizing the human body and affecting access to health care negatively is unacceptable. [136]

6.2.2 Increased costs

Pre-directive saw the enforcement of highly aggravated farmers who were arguing that the directive would result in higher prices and lower incomes for the individual farmer. The fear behind this discussion is that biotechnical advances within agriculture will be too expensive and therefore not available to the smaller farmers with less money[137] which risks resulting in smaller farmers being less competitive due to the fact that they cannot access modern agricultural technologies. By extension this risks meaning that smaller farmers would be forced out of the agricultural sector. In a report on the effect of gene manipulated crops in less developed countries it is presented that the prices of the seeds for gene manipulated crops are very high and that the price is related to the number of years which the patent is upheld in a

[135] www.smer.se/Bazment/183.aspx accessed on 2011-10-26.
[136] Ibid.
[137] Singh et alia, World Patent Information 2009.

country.[138] The patents on genes in the agricultural sector can be used as a means of locking single farmers out of new technologies that larger competitors can afford and thus will have access to.

It seems as though at least part of the prospective effect on agricultural products has become true as reports on raised seed are readily found[139] and record revenues for agricultural companies are reported.[140]

6.2.2.1 Myriad genetics

The concern for increased costs presented in the previous section can also be applied to discuss gene patents for pharmaceuticals. The company Myriad Genetics has held the patents in Europe for human breast cancer and ovarian gene called BRCA1 and BRCA2 since 2001 and 2003 respectively[141] and in the US since 1997[142]. Myriad produces a test which shows the patient whether they are a carrier of the breast and ovarian cancer gene costs $3340 per test in the US rendering it virtually inaccessible to many.[143]

In the US the patent held by Myriad genetics has raised a huge debate on the admissibility of patents on human DNA in relation to an individual's right to have access to pharmaceuticals. The debate was instigated when Genea Gerard was diagnosed with breast cancer in 2006. She was then tested to see if she was also at risk of developing ovarian cancer and the test result was positive displaying a high risk of developing ovarian cancer. Genea then wanted to take another test in order to get a second opinion but her insurance company refused to pay for it on the grounds that it was too expensive.[144] The test was based on the gene patent which was held by Myriad Genetics. Joined by other cancer patients and organizations, amongst others the American Civil Liberties Union (ACLU) Genea filed a lawsuit urging the courts to remove Myriad Genetics patent. The ACLU later expressed in a press release that they had filed the lawsuit because: *"Gene patents undermine the free exchange of information and scientific freedom, bodily integrity and women's health".*[145]

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[138] Qaim, American Journal of Agricultural Economics 2005, p. 1320.
[139] Kaskey, Bloomberg, 2010.
[140] www.forbes.com/sites/afontevecchia/2011/06/29/amid-record-high-food-prices-monsanto-grows-q3-profits-77/ accessed on 2011-12-21.
[141] Matthijs, Familial Cancer 2006 p. 96.
[142] von der Ropp & Taubman, WIPO Magazine August 2006.
[143] Pollack (I), The New York Times August 24th 2011.
[144] Schwartz, New York Times May 12 2009.
[145] BRCA: Genes and patents, American Civil Liberties Union May 27th 2009 Accessed via www.aclu.org/free-speech/brca-genes-and-patents#13 on 2011-12-15.

In federal court the patent was revoked on the grounds that the judge found that patents on genes are against the laws of nature[146] However in the court for appeals for the federal circuit the patent was upheld where the courts argued that isolated DNA is something separate from the DNA which is found in the human body.[147] Thus the court of appeals adhered to the ruling of the Supreme Court in the case *Diamond v Chakrabaty* allowing for continued patent protection for genes. If the ACLU and other plaintiffs will appealed to the Supreme Court is uncertain at this time.

Patent litigation is not an unusual concept but the norm is that the process revolves around infringement or third parties claims that the patent does not fulfill the criteria for patentability. Instead the Myriad genetics case is a law suit which deals solely with the accessibility to medicines and the hindrance that gene patents result in with regards to access to medicines. The case is thus not a case dealing with infringement or unlawful patents but instead this case is in regards to policy.[148]

6.2.3 A gene does not fulfill criteria for patentability

As mentioned earlier a product has to be industrially applicable, new and inventive in order to fulfill the criteria for patentability. During the implementation of the directive and throughout EPO case law the criteria for patentability have been expanded in order for genes to fit into the mold of what has previously been patentable. Some, however, argue that this expansion is too wide and that including genes in patents means that one has removed the criteria required of a patentable object.

What is often argued is that genes in patents are far from what occurs in nature since the gene has been so far synthesized that it can no longer be compared to what occurs naturally. However, others argue that what is actually changed about the gene is that useless information in the form of un-coding introns[149] is removed which actually only changes the appearance of the gene, and not the function in itself.[150] This means that removing some introns does not make the gene new or non-obvious thus not fulfilling the basic criteria for patentability.

[146] Schwartz & Pollack, New York Times March 29 2010.
[147] Pollack (II) New York Times July 29 2011.
[148] Press conference statement by Cook-Deegan, Director of Duke University's Institute for Genome Science & Policy's Center for Genome Ethics, Law & Policy - www.youtube.com/user/DukeIGSP accessed on 2011-12-08.
[149] *A nucleotide sequence.*
[150] Koepsell, IP Watchdog online magazine, 2009.

6.2.4 Gene patents hinder research

One of the strongest arguments against gene patents is in regards to its effects on research. Some fear that allowing these patents will make research more costly and less efficient due to the monopoly on certain genes and the need to form licensing agreements before using a patented gene in research.[151]

In a US survey from 2003 53 % of leading laboratory directors said that they chose to not pursue a certain area of research due to risk of patent infringement.[152] In the same survey 25 % of laboratory directives said that they had received notification from patent holders to resume from performing research in a specific field.[153] These results are hardly surprising considering that a report from 2005 shows that over 20 % of the human genome is patented in the US.[154] These results show an almost inevitable clash between patent holders and researchers where the patent holders wish to protect their patents while researchers and by extent, the public, might find it more beneficial if genes were accessible to all.

7. The Monsanto case

7.1 Background: Monsanto history

Monsanto is an American agricultural company which has existed in its current form since 2002.[155] The company's history dates back to 1901 but it was in 2002 that Monsanto was created from the agricultural division of the Swedish-American company Pharmacia.[156] Monsanto is a considerable corporation with facilities all over the world.

Monsanto has been notorious internationally for many years. For instance; Monsanto was one of the companies which supplied the American army with Agent Orange during the Vietnam War.[157]

To allow the reader an idea of Monsanto's size it can also be mentioned that in 2011 Monsanto placed as number 234 on the Fortune 500 lists.[158] This list is compiled annually by the Fortune magazine and depicts the 500 companies with the largest gross revenue.[159]

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[151] Borger, The Guardian 1999.
[152] Cho et alia, American Society of Investigative Pathology 2003.
[153] Ibid.
[154] Jensen & Murray, Science 2005.
[155] www.monsanto.com/ accessed on 2011-09-19.
[156] www.monsanto.se accessed on 2011-09-19.
[157] www.monsanto.com/newsviews/Pages/agent-orange-background-monsanto-involvement.aspx accessed on 2011-09-19.
[158] money.cnn.com/magazines/fortune/fortune500/2011/snapshots/11092.html accessed on 2011-09-19.

Since 2002 the reformed Monsanto has focused solely on agricultural products. Within the area of agricultural products Monsanto are well known for creating crops which are more resistant to pests and which grow more voluminous then regular crops, simply put Monsanto has focused a lot of their business on creating Gene Manipulated Organisms (GMO).[160]

7.2 Background: the case

Monsanto has held a European patent for a gene sequence that makes soy beans resistant to pests since 1996; the system is named Roundup Ready by Monsanto. This gene has been introduced into soy beans and sold throughout Argentina for several years, notably however, Monsanto did not hold a patent for the gene sequence in Argentina. During 2005-2006 flour produced out of this soy bean was imported into the Netherlands.

Monsanto requested that tests be performed in order to determine if the flour contained the genetic materials for which they held the patent in Europe. After testing it was concluded that the soy flour contained segments of the DNA which Monsanto had patented. [161]

Monsanto brought the case to court in The Hague and this court referred the question about the extent of a genetic patent according to the biotech directive to the European court of Justice (ECJ).[162] This case is interesting partly because it is the first case within the scope of biotechnology which has been brought to court since the directive was implemented but also because this case focuses on the scope of protection for gene patents in deviation for the norm of European case law which focuses on criteria for patentability.

7.3 The ECJ's verdict

The Dutch courts referred four questions[163] to the ECJ:

1. Is article 9 of the directive to be interpreted as providing protection for a genetic sequence even when that genetic sequence no longer holds a function in its current state but may possibly perform a function again if extracted and inserted into another organism?

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[159] www.uspages.com/fortune500.htm accessed on 2011-09-19.
[160] See for example Hedelius, Svenska Dagbladet, May 30th 2011.
[161] Press release by the ECJ europa.eu/rapid/pressReleasesAction.do?reference=CJE/10/73&format=HTML&aged=0&language=EN&guiLanguage=en Accessed on 2011-09-19.
[162] ECJ case number C-428/08.
[163] C-428/08 point 32.

2. Does article 9 in the directive lead to a hinder in allowing absolute protection of a genetic material according to national law independent of if the DNA is performing a function or not and is article 9 of the directive exhaustive in this situation?
3. While answering question 2; is the fact that a patent was granted before the directive was adopted have any relevance when an absolute product protection was in place according to national laws?
4. Is it possible to regard the TRIPS agreement and particularly articles 27 and 30 while answering the above mentioned questions?

7.3.1 Question 1

Article 9 of the directive states that:

"*The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material…in which the product in incorporated and in which the genetic information is contained and performs its function.*"

During its ruling on this question the court takes a very literal approach towards the wording in article 9 of the directive. The court notes that the use of present tense in article 9 of the directive *"material…in which"* should be interpreted as an indication of that the function of the DNA has to be active if Monsanto should be able to claim that an infringement in their patent rights has taken place. The court also concludes that an herbicide is without function once the soy bean has been transformed into flour.

The fact that the DNA sequence could be extracted and implanted into another plant where it can perform a function is not in itself a fact that lives up to a violation of article 9 of the directive. However, if the DNA was to be extracted and implanted into another biological material the courts do not deny that this will give rise to a situation where an infringement could take place in regards to the patent and the new biological material.

Furthermore the court points towards the limitation in article 23 of the preamble to the directive where it is stated that a DNA sequence which does not hold a function cannot be protected via patents. Moreover article 5(3) of the directive holds the same intention that genetic sequences lacking in industrial applicability cannot be awarded patent protection. Article 23 of the preamble, article 5(3) of the directive and article 9 of the directive in tandem mean that a DNA sequence which does not hold a function cannot be awarded patent protection.

The court thus concludes that a DNA sequence which does not hold a function in its current state cannot be awarded patent protection independent of if the product could be extracted and placed into another organism where it once again would serve a function.

7.3.2 Question 2

The court answers question 2 by reviewing the preamble to the directive. Firstly the court points towards recitals 3, 5 and 7 in the preamble to the directive. Herein it is stated that it is necessary to create harmonized legal protection for genetic inventions to encourage investments in this field and that the lack of harmonization which existed risked creating barriers to trade. Collectively the above mentioned recitals point towards the need for harmonization in order to encourage trade on equal terms within the European Union.

Furthermore the court views recitals 8 and 13 in the preamble to the directive where it is stated that there is no need for the member states in the European Union to create a separate law regarding biotechnical patents and that the national law remains the basis of patentability pending that they adopt their laws to conform to the directive. The recitals also state that the community's involvement can be limited to certain principles. From recitals 8 and 13 it can be concluded that the European parliaments aim with this directive was to harmonize the member states legislation without interfering in the material law in any separate member state. The court stresses that the aim of this directive is to harmonize the member states legislation in order to remove barriers to trade and optimize the balance between patent holders rights and others. Whilst stating that the directive wants to enforce minimal changes on the member states the courts also point towards article 1(1) sentence two which requires nations within the community to change their legislation in compliance with the directive.

The court concludes that because of the above mentioned, member states may not include infringement rights under unlimited protection to genetic material when the gene does not perform a function; article 9 of the directive is exhaustive.

7.3.3 Question 3

The court answers this question by referring to the case *Commission* v *Freistaat Sachsen*[164] and in this case the courts refer to *Brock*[165] and *Licata* v *ESC*[166] where it was settled that old rules are replaced by new legislation regarding future settlements. By referring to these cases the courts hold on to this well established principle which over-rides old legislation to allow

[164] ECJ case C-334/07 paragraph 43.
[165] C- 68/69.
[166] C-270/84.

consistency throughout an entire legal system. If the courts were to treat different patents differently depending on when they were registered the system would become too complex to uphold. New legislation would also become very difficult to enforce if those rules were not applied to registered patents since this would mean that it could take up to 20 years until the new rules were applied on all registered patents.

The court clarifies that the directive does not allow for any deviations and that if different patents were to follow different rules then this would lead to a hinder in the harmonization of the member states legislation regarding biotechnical patents.

The court concludes that the fact that a patent was registered before the nation signed the directive does not allow the patent holder absolute protection as it was structured under national law at the time when the patent was granted.

7.3.4 Question 4

To clarify, the court starts by stating that the TRIPS agreement does not give individuals rights which can be brought before the court which has previously been stated in the cases *Dior and Others*[167]. However, it is also pointed towards that even if there is EU legislation in place then that rule shall be viewed in the light of the TRIPS agreement in accordance with the case *Merck Genéricos - Produtos Farmacêuticos*.[168] The directive is to be considered European Law and should therefore be interpreted while keeping the TRIPS agreement in mind.

Article 27 in TRIPS declares which areas should be subjected to patentability and article 30 states exceptions to the rights attached to patents. In this case the court chooses to interpret *"exceptions to rights conferred"* in article 30 as harboring both exceptions to right as well as limitations to these rights. By this logic the court finds that article 9 of the directive is compatible with articles 27 and 30 of the TRIPS agreement.

8. Developments so far

As mentioned above the directive was intentionally left unspecified in order to allow the separate member states to formulate their own interpretations of the directive. Its objection was to harmonize European patent law and to create financial incentive for corporations researching on genes. However, by merely creating a frame work and leaving the legislative duties to the member states the European Parliament also created many areas of unclearly and

[167] C-300/98 and C-392/98 paragraph 44.
[168] C-431/05 paragraph 35.

loss of structure. If the aim was to harmonize European patent law the question is if the best way of doing this was really by implementing such a vague directive?

It might seem as though the initial assumption regarding the gene patents was that the rights conferred were virtually unlimited. However, as has been discussed above, there are factors which have left the scope of patent protection diminished. The question which will be focused on in this chapter of the essay is the scope of patent rights and how the Monsanto case has affected the judicial status of genetic patents.

8.1 A balanced system?

A patent has dual functions; on one hand a patent allows the inventor and patentee the right to protect their investment and invention and on the other hand a patent also allows the spreading of information, facilitate access to information and encourage research.[169] The purpose of the patenting system is to create a balance between financial investments, innovation and access to new technologies at a reasonable cost.[170] The aim of the patenting system is that an invention should be protected but at the same time the public has the right to access the information in order to utilize it after the term of protection has elapsed.

Acquiring absolute patent protection for a gene is slightly different from what is discussed above. As has been mentioned earlier an absolute patent protection entails an expansion on the normative scope of protection where the scope of protection is not limited by the current invention and use of that invention but also includes areas of application which may not be known when the patent application was filed.

Even though possibilities like licensing and compulsory licensing are available it is necessary to reflect upon if the system concerning gene patents is actually balanced. The question of if the rights assigned by the system actually match the scientific achievement of purifying a gene arises. Since the rights attached to gene patents are vast many would argue that the protection within this form of patent is too extensive. One must remember that allowing patent rights for genes was, and is still, disputed and by allowing such an extensive portfolio of rights the regulations might be found to be too generous. Even if the ethical elements of allowing gene patents were ignored the question of if the genes constitute a patentable matter still remain where many argue that discoveries should not be patentable since this extends the patent system too widely and thus supersedes the established constraints of patents. As has

[169] Bavec & Raspour, Food Technology and Biotechnology 2002 p.358.
[170] Swedish preparatory works Proposition 2003/04:55 p. 47.

been mentioned before many biotechnical companies and others who are pro gene patents argue that that genes do not constitute mere discoveries as the matter is greatly purified before being up for patentability. However the subject is highly volatile and adding an extensive protection system could also be questioned and cause those who are displeased with the system to gain fuel for the fire. The reader must remember that allowing absolute patent rights for genes was allowed in order to mimic the protection allowed for chemical compounds; however this is not necessarily the obvious and most successful choice for this type of element. Instead, it might be more natural to limit the scope of the patent to only include the proteins which are listed in the patent application. Fundamentally there is a difference between allowing one type of protection for a chemical molecule which has been developed in a lab and allowing that same protection for a gene which exists naturally. Even though the process of synthesizing genes and developing chemical compounds might be similar regarding the labs technical work there are several more factors that supersede financial investments which should be considered.

Regarding the rights inferred by the directive it is difficult to find the actual limits of the absolute protection of genes as these are continuously tested in court. The development through case law will probably continue for a long time before the limits to gene patents and a balanced system can be crystallized.

8.2 The interlink of the US and EU

In order to clarify the background to the directive and the mood in which it was launched it is important to note the development of the law concerning biotechnical inventions. The development which lead to the directive did not start in the judicial arena but instead in the administrative arena via patents allowed by courts in the US (see *Diamond v Chakrabaty*) and by the EPO in Europe. It seems as though the legislative arena has followed the administrative which might be an indication of that the development is not thought through but is instead forced by biotechnical companies.[171] As has been mentioned earlier the directive was introduced largely as a result of the financial interests of agricultural and pharmaceutical companies in the US in order to assure the development of investments and research by these institutions. The development within the US was later followed up in Europe by the case law of the EPO. However, it is important to acknowledge that the EPO is not a part of the European Union but is an independent administration concerned solely by the protection and development of European patents. The European Parliament then followed suit by introducing

[171] Pamp, Intellectual property in Science, p. 213.

the directive in order to harmonize European patent law and to strengthen the position of biotechnical patents in Europe.

The judicial development within the US and within the EPO basically left the European Parliament without the possibility of choosing to harmonize the member states legislation via the directive. In order for Europe to remain competitive with the US within biotechnology the EU had no choice but to empower European pharmaceutical companies with the ability to patent their genetic discoveries through the member states national law.

Within the EU and Sweden the possibility of lobbying is admissible but it's hardly as established or organized as it is in the US. In the US lobbyists are protected under the US Constitution's first amendment by the right to free speech, assembly and the right to petition.[172] Lobbyists give testimonies and provide information to the congressmen and women who later chose to vote to stop or pass a bill. The ability to provide the congressmen and women with information and supply testimonies from experts is largely dependent on large funds. For example drug and pharmaceutical companies were estimated to have spent $110 million in the half of 2009.[173] This entails that large pharmaceutical companies with large funds will be able to have their voices heard to a much larger extent then a non-profit organization trying to voice the ethical debate on gene patents to congressmen or women. The system of lobbying seems unjust in the sense that the depth of the pocket becomes equal to the strength of voice with regards to new legislation or support of praxis like in regards to genetic patents. It is important to keep in mind that companies who research genes are, in many cases, some of the largest and financially strongest corporations in the world.

As Europe was driven to follow the US in order to allow European Pharmaceutical companies the chance of keeping up with developments in the US the question remains: was the permission of gene patents really the best option or was the hand of the legislator too influenced by strong financial interests?

8.3 The effect of the Monsanto case

After the case was settled Monsanto, via a press release on their web site, stated that the aim of the claim was merely to make Argentinean companies pay for using Monsanto's technology for free.[174] Disregarding Monsanto's claim the courts verdict was that gene patents

[172] Can be viewed on for example www.law.cornell.edu/constitution/first_amendment accessed on 2011-11-14.
[173] Tumuly & Scherer, Time 2009.
[174] Argentine Soy Meal Imports www.monsanto.com/newsviews/Pages/argentine-soy-meal-imports.aspx accessed on 2011-11-13.

could not be enforceable on products where the gene does not have a function, which it did not have in this case. If the gene is merely present in the product but does not actually perform a function the courts interpreted that the directive does not encompass the basis for an infringement claim.

The ruling has been interpreted as showing a clear support for gene patents while stating that the directive should be interpreted narrowly in cases like these.[175] Monsanto's claim was an over-reach of the scope of patent rights in this case. However, what becomes interesting is that the limits applied by the courts was not apparent before the case even though some have stated that the ruling was not surprising[176] this case is the first clear statement issued surveying the limits of the directive. The case was administered by the ECJ's grand chamber of 13 members which signals that this judgment was one of great interest and importance to the development of gene patents within the EU. Interestingly the Dutch importer and Monsanto had come to a settlement before the case came to court but the ECJ chose to fulfill the proceedings and pass judgment.[177] By issuing a verdict even though the case was settled the ECJ display that there is s need to crystallize the limits to the scope of gene patents in order to create a more predictable and stable environment for gene patents.

The effects of the ruling could be that there is an increase of imports of processed products from countries with weak patent systems.[178] This does risk resulting in the courts actually legitimizing countries outside of Europe, with patent systems which are not equal to the ones within the EU, to flood Europe with cheaper products. Even though the aim of the directive was not explicitly to hinder this development it is unclear if the risk of encouraging countries without the same level of gene patent protection was calculated by the ECJ. The risk might not be overwhelming but the implication could be interpreted as encouraging European based corporations to produce crops and process them outside of Europe in order to import them into Europe when the DNA has reached a stage where it no longer performs a function. This could result in agricultural companies relocating their production outside of Europe in order to avoid paying licensing fees to companies which hold the patents. It is however important to note that no such developments has yet been observed.

[175] Marshall, Science July 7th 2010.
[176] Ibid.
[177] Conley, Genomics Law Report, 2010 via www.genomicslawreport.com/index.php/2010/07/28/european-court-issues-gene-patent-ruling-against-monsanto-a-myriad-connection/ accessed on 2011-12-19.
[178] Miller, The Wall Street Journal July 7th 2010.

8.4 Summary

As has been discussed above the directive was enforced in order to allow the European biotechnology to compete with the US industry. The basis for introducing genetic patents in the US was undoubtedly financial where pharmaceutical and agricultural companies had a strong influence on the current legislation. In order to reach the level of protection applied to US gene patents and thus compete within the same realm the scope of protection for gene patents must be equally strong within Europe.

The result of the parliaments strive to compete with US and EPO case law has lead to a patent protection which is so strong that it extends beyond the goal of a balanced patent system. The absolute patent protection allows for a very broad protection and it seems that the voices of those opposed to gene patents were not adequately considered while creating this patent system.

Due to the fact that the directive has been formulated so openly this has lead the European member states without clear directives on how to delineate gene patents. The extensive protection awarded by the US and EPO have also affected the scope of protection of gene patents. The judgment in the Monsanto case awarded Europe with at least one clear line drawn: when the patented material is no longer functional the scope of protection does not include this state of DNA. Even though some argued that the judgment on the case was obvious it is important to note that with these types of judgment come clearer limitations on the scope of rights attached to genetic patents. Through this judgment the ECJ clarify that even though the concept of gene patents is still upheld its realm of protection is not without limits.

9. The future

Predicting the future of gene patents may appear to be a precarious exercise. However, the fact that the law tends to develop at a much slower rate than technology makes predictions beneficial. This argument rings especially true when the field of biotechnology is discussed since this is a market which generates enormous revenues and which thus has the capacity of developing at a very fast pace. This can mean that the laws which were designed for a type of gene patents are soon applied to developments which the law was not originally designed for. The fast pace of research development in relation to the slow evolution of laws makes for an area which is greatly in need of predictions for the future.

9.1 Important advances

As was mentioned earlier in the essay the possibility of patenting genes has been a reality since the 1980s when the US court upheld the first patent on a GMO in *Diamond v Chakrabarty.* This case became a landmark and soon the possibility of patenting genes was a reality in Europe via the EPO.

The first years of gene patents saw for a flooding of patent applications into the patent offices. During the period 2001 to 2003 there were two great developments which altered the field of European gene patents. The first change was the EPOs ruling in the ICOS case where the possibility of patenting genes saw a heightening of the criteria for industrially applicable. This case saw the EPO raise the bar for the information which was required to be provided in the patent application demanding a specified area of use instead of a more speculative area of application. The second change was provided by the HGS project which was completed in 2003. This project presented a mapping of the human genome and with its unveiling came a raised bar for patenting human genes. Even though the HGS project only concerned human genes it has had a considerable impact on the area of gene patents as many of these types of patents are regarding human genes. As a result of the two mentioned incidents gene patent applications have been said to decrease greatly.[179] The result has been that patentees are more careful in their patent aspirations waiting longer before they patent because they are aware of the raised demands of patent applications.

Herein it is also relevant to note that there are a finite number of genes which can be patented. This means that even though the HGS project and ICOS case had a great effect on the ability to patent genes the diminishing amount of patent applications are natural due to the fact that there is simply a steadily diminishing pool of genes which fulfill the criteria set up by the directive and the EPC. It may be that the HGS project and ICOS case caused the rate of decrease of patent application to be brought nearer in time but the development would have happened at some point in the future due to the nature of genes.

9.2 Conclusions on the case Myriad Genetics

It is appropriate to discuss certain developments within US case law since it was the US who introduced the acceptance of gene patents which Europe then followed through the EPO and the directive. It is important to note that Europe, in order to be competitive within the field of biotechnology, is and has to be influenced by the developments in the US.

[179] Engineer Patrik Andersson at the Swedish Patent and registration office states this in a phone interview/discussion 2011-11-21.

When gene patents were first allowed in the US in the 1980s the patent office was flooded with patent applications on genes. In 1999 the United States Patent and Trademark Office (USPTO) released stricter guidelines[180] regarding gene patents. These guidelines state for example that:

"If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility if ... the utility is specific, substantial, and credible".[181]

The EPO have not directly followed suit by addressing these demands within the EPC but through the ICOS-case the EPO seem to fall in line with the USPTOs guidelines since the EPO also require that the patent application needs to have a specific area of industrial application for it to be accepted. It's imperative for the reader to understand that Europe is constantly affected by US developments within the area of gene patents.

The case Myriad Genetics has already been discussed but the repercussions of the case and how it may influence the future for gene patents has so far been overlooked. The Myriad Genetics case can be seen as an uproar towards the strength of gene patents directly affecting the human health as large organizations like Association for Molecular Pathology, American College of Medical Genetics and American Society of Clinical Pathology alongside several individuals[182] filed the claim against Myriad demanding that the patent be revoked. This case has given fuel to the fire on the debate on human gene patenting[183] and the effect which is withholding access to health care due to high prices which are a result of the patenting system. Many individuals and organizations simply find that genes should not be patentable and looking at the development of stricter criteria for patents the laws appears to agree with the naysayers. The fact is that the patentability of genes is based on a legal construction where the term invention is defined differently than how it is used in everyday language. The patentability of genes may be too abstract for the general public to accept which can be seen as the reason to why the debate on patenting genes has been current for such a long time. The ability to patent genes has been available for thirty years yet the public and several legal actors still have a hard time accepting the repercussions of the system. What's important to note with regards to the debate which has been fuel by the Myriad case in the US is that it not an accepted system of patenting which can be deducted on the basis that partly the media

[180] USPTO Guidelines for Examination of Applications for Compliance with the Utility Requirement.
[181] Section II A (3).
[182] Case 09-cv-04515.
[183] *For example* Anderson, h+ magazine October 26 2009.

storm which has occurred as a result of this case and the fact that the judge in first instance ruled the patent to be invalid.

Notably the US Government submitted an Amicus Curiae[184] brief stating that their view was that isolated but otherwise unmodified genes should not be patentable since they should not be considered inventions.[185] This entails that patenting genes is not a system which is fundamentally supported throughout the public or throughout the judicial system.

Within the scope of the Myriad case it has also been argued that the expensive tests provided by Myriad Genetics could be provided more efficiently and a lower cost in an open market.[186] One of the main arguments for gene patents is the incentive to research which can be counter-argued by the high product prices which arise when only one company produce a product. It may be that merely viewing gene patents as an incentive to research is too simple and instead the legislator should also consider the aftermath of awarding monopolies on genes. The result of gene patents could be that it encourages primary research but then stifles development within the patent which has been awarded. It's the lack in access and the lack in development which has people and organizations angered and fighting back. As mentioned before the US and Europe are interlinked which results in ripple effects on debates taking place in the US which then soon reach Europe. This may result in a re-fueling of the debate on the extent of protection on gene patents in Europe as well.

9.3 Conclusions from the Monsanto Case

Even though the outcome in the Monsanto case may not have been unexpected the case falls in line with a number of legal and administrative measures taken in order to limit the distribution and scope of protection for gene patents. Since the area of gene patents is relatively new it is constantly developing which means that we will probably see cases in the future which may seem apparent but to which the legal sphere cannot offer answers to prior to the court's ruling. What is imperative regarding this case is that it, along with many other administrative and legal aspects, fends back the scope of gene patents when those in possession of gene patents try to expand the scope. In relation to the scope of patent rights it may be appropriate to quote Baron Acton *"Power tends to corrupt; and absolute power*

[184] *Amicus Curiae briefs are briefs containing information which are submitted to the courts by someone who is not a party in the trial.*
[185] Amicus Curie Brief by the US Government www.genomicslawreport.com/wp-content/uploads/2010/11/Myriad-Amicus-Brief-US-DOJ.pdf p. 17f accessed on 2011-11-25.
[186] Pollack (I), New York Times 24th August 2011.

corrupts absolutely. Great men are almost always bad men".[187] This quote may seem misplaced within the realm of this essay but the point is that there is a need for powerful companies patents to be controlled as Lord Acton says in his famous quote, otherwise they will aim to expand the scope of patent rights as far as possible. Monsanto is a vastly powerful company as are many companies which are in possession of gene patents.

Besides the court's ruling the case illustrates that biotechnical companies will strive actively to expand the scope of their gene patents. As the area of gene patents is developing quicker than the laws it is important for administrative arenas and judicial arenas to cooperate in order to restrict that development in order to strive for a balance between invention and protection within the patenting system.

9.4 Future within biotechnology

The legislation may find the case law and legislation which has developed within this area may be considered adequate for the type of research which is possible today. It is, however, important to note that science tends to evolve quicker than the law and that the scientific community benefitting from research have great resources to develop beyond the realm of what is scientifically possible today. Most of the administrative and judicial developments to gene patents are in relation to higher demands on the criteria to patent which might be inadequate considering the biotechnical progress which is within grasp.

Section 2.2.2 mentioned the ability to apply gene therapy in order to exchange a diseased gene with a health gene and thus eliminate a genetic disease in a person. Currently zygotic gene therapy is not conducted or allowed on humans, however, the thought of being able to permanently change a feature on oneself which a person does not wish to pass on to its children will probably seem appealing to many. The reader should also be aware of the fact that zygotic gene therapy is not limited to being applicable in case of genetic diseases it could also be used in more superficial cases to example change the size of one's nose or some other cosmetic feature of a person. The skeptic might point towards the fact that many physical and mental characteristics are dependent on several genes in combination with the environment; however, there are trials in animals which have displayed the effect of altering single genes. For instance a gene was changed in a fruit fly followed by adding a certain chemical to the fly's food, these two in combination caused the fruit fly to learn five times faster than if the

[187] Acton, letter to Bishop Mandell Creighton in 1887.

gene had not been changed.[188] Another illustrative example is that scientists believe they have found a gene where carriers become tone deaf.[189] The problem which arises is that the future holds a limitless possibility to change the genome. There are many prospective parents who would most likely be prepared to pay large sums to guarantee that their children do not carry genes coding for Alzheimer or on a lighter note: tone deafness. Where there is a paying market there is also research companies lining up to develop a product which will generate revenues.

There are alterations which can be made to animals and people which could enhance physical and mental performance. The point is that it already, at least theoretically, lies within grasp to provide individuals with a more powerful genome which ultimately could mean that gene patents would provide certain pharmaceutical and agricultural companies with a heightened power. This prospect may be compared to the earlier mentioned Eugenics movement which had dire consequences for many. The Eugenics movement was a crude attempt at gene therapy but is important to recognize that the tampering of genetics in order to create a stronger race is something which has existed for over 100 years and which is fascinating to many. As has been mentioned before the patenting system is meant to provide incentive to research but allowing for a higher level of protection and thus a higher level of profit may cause incentive to develop genes further than many people realize.

9.5 Summary

The development of gene patents so far appears to be a slow but steady decreasing of when a company can apply for a patent and its corresponding patent rights. Due to several aspects, discussed above, the gene patent scope has decreased and it has become increasingly difficult for research facilities to gain a gene patent. The future will most likely entail future developments in this direction where patentability of genes will continue to be limited by the outcome of the ICOS case and the developments through the HGS project. It seems highly unlikely that the EPO or USTOP should be willing to reverse the development and aim to facilitate gene patenting further since this would mean going against a growing public opinion. As was mentioned above the Myriad Genetics case has gained great media coverage which will form public opinion, irrespective of the accuracy of the articles they still have great effect on public opinion on gene patents.[190] As laws are supposed to be a codification of

[188] Brändén, Genteknik, kloning och stamceller p. 94.
[189] Ibid. p. 96.
[190] Morrisson, Biotechnology Law Report 2010 p. 609.

societies morals and ethics it would most likely be too risky to change the restrictive development of gene patents which has been occurring during the last ten years.

As a result of the media coverage of the Myriad Genetics case the Secretary's Advisory Committee on Genetics, Health, and Society ordered a study to be carried out by Duke University aiming to result in an answer to the question: are gene patents beneficial to research?[191] The report concludes that the application of gene patents is too broad which, in some areas, stifles research instead of encouraging it.[192] This report is interesting because the incentive to research has been the strongest argument for gene patents, but instead this report says that in certain cases the gene patent system actually harms progress.[193] The report is still relatively new which means that the aftermath of its results are not possible to view yet but the chance is that this report may stifle one of the main pro-patent argument placing a new light on the discussion of the scope of protection of gene patents.

It was hardly reasonable to expect the higher courts of justice to render Myriads patent on genes unlawful because this type of decision would have great repercussions by throwing the legitimacy of gene patents into uncertainty. If the courts wish to restrict gene patents further this development will most likely be performed more gradually.

From articles discussing the Myriad Genetics case it seems as though many still favor the human rights aspect of the gene patent debate arguing that genes should be accessible to people. A popular point of view is that individual pharmaceutical or agricultural research companies should not be able to own a certain gene resulting in isolating humans from access to effective health care or optimizing crop growth. This point of view is in line with Tauri's theory on critical legal positivism where gene patents are a relatively novel concept which has not had time to sediment through the layers of the law and reach the same status as human rights has.

The reader should be aware of the openness which remains in the gene patent system today. An absolute product protection is available for those who meet the criteria which leaves the floor open for companies to develop genes where there are not currently exceptions in the law. The gene patent system is, at least in theory, an unbalanced system allowing for a greater realm of protection in proportion to the discovery made. Even though the system may appear to be relatively balanced today it is imperative to watch the horizon for gene developments

[191] R Cook-Deegan & Heaney, Genetics in Medicine 2010 supplement p. 1.
[192] Greenemeier, Scientific American 2010.
[193] Evans, Genetics in Medicine, 2010.

which may be applied to gene patents allowing the patentee a large scope of protection. The gene patent system is relatively new and according the theory on critical legal positivism sedimentation is slow, however, if the future is to hold a balanced patent system for genes then the changes to the legislation need to be enforced at present in order to allow the changes to graduate throughout the system to settle in the deep structure of the law.

10. Conclusions

From the beginning of gene patents it was assumed that the best way of providing incentives to private research institutions was via allowing the patenting of genes. This argument has then followed the debate on gene patents and has always been fronted as one of the main incentives to the continued patenting of genes. The truth is that the argument is highly valid as the price tag on biotechnology is staggering. The biotechnology industry needs private investors in order to maintain research and in their turn these investors need assurance that their investments are protected.

In contrast to the financial incentives in biotechnical companies are the interests of individuals. It has long been assumed that patenting genes is necessary in order to ensure biotechnical progress. This biotechnical progress would then directly benefit individuals in the form of new advancements. Currently this assumption seems to be somewhat too simplified to suit today's debate. As the Duke report shows it may be in the public interest to actually differentiate between the use of different forms of gene patents and award different scopes of rights for different areas of application. The impact that the report will have on the patenting system is yet too early to determine. It is, however, clear that the report presents a view which has so far been overlooked leaving the system of patenting gens undiversified. Even though the Duke report entails that a more diversified system of gene patents may be scientifically efficient it does not provide an answer to how the system should be changed. As was noted in the Swedish Official Reports, the patent system is notably unbalanced but trying to create a more balanced system would be practically difficult and very costly thus not constituting a viable option.

There is an important point to be made in getting the public on board with gene patents. As has been displayed in the US, public opinion can influence the future of gene patents which became clear when viewing the amount of media coverage that the Myriad case attained. There is still a great distrust against the concept of owning genes which, at least in part, lead to the Myriad case. The case has gained great media coverage whereof some have criticized

the information being spread by news papers as being faulty and lacking in judicial correctness.[194] When the US government sent in an amicus curiae brief it became apparent that this distrust permeates several levels of society. The media coverage appears to have spread greatly exclaiming that the Myriad test is both inefficient and costly.[195] Media is naturally focused on gaining attention and may thus benefit from twisting the issue into something which will cause public stir. The discussion in the US does, however, clearly show that the issue of gene patents, especially in humans, is something which many tend to find difficult to accept from ethical, legal and humane perspectives.

The Monsanto case was the first verdict after the biotechnical directive was presented. The fact that so many years have passed since the directive was implemented and the first ruling is in itself a reflection upon that the directive is merely a codification of rules which were already a reality in large parts of Europe via the EPO and national legislation. The case in itself is a slight limitation of what appears to be a very optimistic filing from Monsanto. It seems that Monsanto's claim encompassed a wish for Europe to compensates for other Argentina's lacking patent recognition which is hardly the aim presented in the directive. The lesson to be learned from the case is that Monsanto had incentive to test the boundaries of gene patents and a wish to expand the scope of protection which, in combination, was what lead to the case. Even though the court's ruling was expected it notably closed the door to extending gene patents not non-viable genes while the ECJ showed continuing support for the system of gene patents.

In Sweden, and most EU member states, the theoretical scope of gene patents is extensive since the directive and national legislation supplies the ability to apply for absolute product protection. As has been mentioned above patent applications have diminished as a result of the ICOS case and the HGS project. The fact that this development of patent criteria has taken place in the administrative arena instead of the judicial may in itself be a problem. There are an extensive amount of considerations to take in while deciding on the future of gene patents which extend beyond the realm of financial incentives and which may thus been better processed by policy.

The ethical perspectives will probably never stop being current in this debate which means that there is room for legislators to improve the system in order to reach an equilibrium between the social, financial and judicial. The Duke report shows that there are new

[194] Morrisson, Biotechnology Law Report 2010 p. 609.
[195] *See for instance* Crichton, New York Times, 2007.

considerations to be made in order to optimize the patent system and at the same time the Myriad debate reflects the public interest in the issue. Rationalizing between the different levels of the law may allow the system to become more unilateral and balanced by incorporating more socio-political views. One idea could be a system where the laws deep structure is prioritized by potentially allowing a greater amount of individual's access to efficient health care or more efficient crops. This could be created by differentiating between the areas of gene patens which have been shown to not benefit from a generous patent system and apply an invention-based patent on those areas instead where the patent would be bound by a specific use and not incorporate the gene in all of its potential uses.

The financial power is undoubtedly a very strong force yet the courts have developed towards more restrictive criteria on gene patent. As of now there are no suggested forms of differentiation between different types of gene patents or figures on what the cost would be to implement a system which is more dedicated towards being optimized at efficiency. What is clear today is that there is a very large benefit to be made for those companies who are able to secure a gene and this is even after the patent system has evolved towards being more restrictive.

The problem remains that with the broad form of protection comes larger incentives to invest. This may, at first glance, appear to be positive and meet the aim of the legislation, however, in the cases discussed above it may also be the large financial incentive which drives the system to expand beyond what it was constructed for by for example perusing less ethical forms of gene therapy.

It could be argued that if gene patents were no longer allowed and that the biotechnological industries would instead have to rely on patents on the final product that this would allow the legislator a larger amount of control over the ethical aspects of the development. This solution would also allow for the industry to gain protection on their end product but not of the gene itself. Naturally the biotechnical industry would argue that this protection would be inadequate in relation to the investments which are made. The question remains if this is completely true regarding all types of patents on genes. Could it instead be possible to separate genes into different categories and apply protection on the basis of what it most beneficial for that individual category? However, this could cause problems with regards to royalty stacking but it may be that the gain of creating a more segmented system for gene patents balances the complications which will be met.

It may be that not all categories of gene patents require the level of protection which is supplied today. It may be as the as the poem quoted in the beginning states, that we can find the best solution between the *"hither and the father shore";* the future may hold the possibility of creating a more refined system which limits the scope of protection to the end product or to the entire gene, depending on what is most efficient while finding a balance between financial, and human interests.

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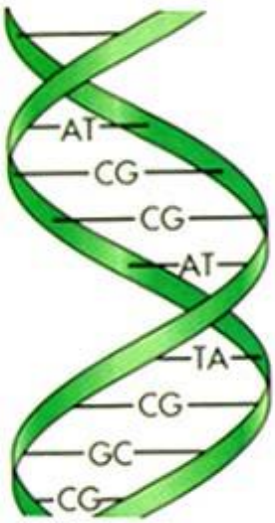
Appendix 1



Illustation of the amino acid pairs which make up a DNA double helix.