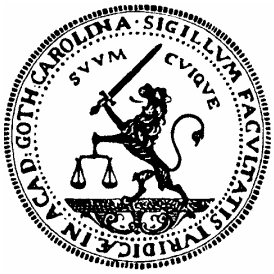

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Patenting Human DNA Sequences

Absolute Product Patents - A Reasonable Degree of Protection?

Abstract: This thesis deals with the patenting of human DNA sequences, and more specifically if today's approach to allow absolute product patents on the human genome is desirable. The thesis presents the ongoing debate between advocators of an absolute product patent, and the most proposed alternative, the purpose-bound patent. I argue that there is no need to introduce the purpose-bound protection due to a better interpretation of the patentability requirements and a fading interest of claiming the DNA sequence per se.

Master thesis
20 points

Hans Henrik Lidgard

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Contents

Summary

The legal controversy on “patents on life” is not new but in the last two decades, we have seen the debate be intensified. Although patents on biological material have been allowed in the United States since the emergence of Diamond v. Chakrabarty in 1980, it was not until scientists at the National Institute of Health tried to patent thousands of gene fragments in the early nineties that the debate was really infected. Today, most people with insight to the patent system agree that the patenting of DNA sequences is an instrumental factor to spur innovation in the biotechnological field and provide a higher standard of healthcare. However, the patent system comes with a cost; it provides a legal monopoly for a certain amount of years for an inventor to recoup the expenses and profit on the invention. While the protection is essential for the patent system to work, the question is: How big of a reward should the inventor receive for his invention? Is it fair to allow protection not only for the disclosed functions of the invention or should the scope of protection be limited only to those functions? Advocators for allowing an absolute product patent claim that a limited protection is not sufficient for the inventor to recoup the expenses and if the inventor cannot profit from the invention he will find no incentives to invest in the field. On the other side are the proponents of a purpose-bound protection claiming that the absolute product patent provides such a broad scope that it deters investors from entering the field anyway.

Product patents are allowed by the EPC and it is not a requirement to allow patents only on purpose-bound basis. However, with the arrival of the Biotech Directive in 1998, many leading experts called for the purpose-bound protection to be introduced. Consequently, when all member states of the European Union finally managed to implement the Directive in national law, we saw many countries that only permitted purpose-bound patents. Amongst others, France and Germany decided to take this approach. The effect of their action is yet to be seen, however it adds an extra dimension to the debate seeing these big and influential countries decide against the absolute product patent.

In more recent time, with the beginning of the issuance of new stricter utility guidelines in the United States in 2001, we have seen a more stringent approach to the patentability requirements that has led to a considerably higher patentability threshold. As a result, the stricter appliance of the patentability requirements and the disclosure requirement now exclude those gene fragments without known utility that money-hungry companies claimed in masses during the “patent gold rush” in the nineties. At the same time, it means that the majority of the patents today are narrower than those issued in the early days of gene patenting, thus giving the inventor a reward that corresponds more appropriately to the contribution made to the society.

The stricter patentability requirements along with the prediction that fewer absolute product patents will be granted due to the subject matter not being able to meet the patentability requirements makes me argue that there is no need to limit the protection given to an inventor should he be able to meet the requirements. Another important factor is that the patenting of DNA sequences per se seems to stagnate, statistics supports the view that most of the claims in the future relating to human DNA sequences will not claim the DNA sequence per se, rather the sequence will be regarded as a part of the invention. In the end, there is a good chance that we will see a shift in the way human genes are claimed without the legislator having to intervene.

Preface

For guidance and valuable suggestions, I would like to thank my supervisor Hans Henrik Lidgard. I also owe many thanks to Timo Minssen, who has helped me more than I think he is aware of. Timo introduced me to the subject in spring 2006 during a lecture in law and economics, and has pointed me in the right direction by introducing important literature and leading cases.

I would also like to acknowledge the support my family has given me, not only in writing this thesis, but during all my time in Lund. Thank you, it is impossible to put into words how important you are to me.

There is one final person that must be acknowledged here. Without her, this would never have been possible:
Pro Anna, Ubicumque Eam Cognoscam

Abbreviations

A	Adenine
Biotech Directive	Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions
BRCA1	Breast Cancer 1
C	Cytosine
cDNA	Complementary Deoxyribonucleic Acid
CPI	Code la Propriété Intellectuelle
DNA	Deoxyribonucleic Acid
EPC	European Patent Convention
EPO	European Paten Organisation
EST	Expressed Sequence Tag
G	Guanine
HUGO	The Human Genome Organisation
JPO	Japans Patent office
NIH	National Institute of Health
OECD	Organisation for Economic Co-operation and development
PhD	Philosophiæ Doctor
Prop.	Proposition
SNP	Single Nucleotide Polymorphism
SOU	Statens offentliga utredningar
T	Thymine
TRIPS	Agreement on Trade-related Aspects of Intellectual property rights
U.S.C.	United States Code
USPTO	United States Patent Office

1 Introduction

Initially, the public debate regarding gene patents sparked little controversy and although patents on microbiological inventions had been granted in the United States since the emergence of Diamond v. Chakrabarty[1] in 1980 it would take until the early 90s before the debate became heated. This coincided with the attempts by scientists at the national institute of health (NIH) to file patent claims on a large number of gene fragments with unknown utility.[2] At the time, quite a few arguments were based on the morality of patenting the human genome, asking questions like who should own life and pointing out that the possibility to patent human genes should be considered slavery. However, some opponents based their arguments not on moral or theological grounds but claimed that human DNA sequences should not qualify as patentable subject matter as they either could not qualify as an invention or should not meet the patentability requirements.

Today, most people with insight to the patent system or the biotechnological field seem to accept that the possibility to obtain a patent is vital for the development of new medicine and continued research on the human genome. Instead, the debate today has seen a shift in focus, from questioning the possibility to patent human DNA-related inventions, leading experts now question the strength of the patents and the type of protection those inventions receive. In the light of the Biotech Directive, the decision by France and Germany only to allow purpose-bound patents on the human genome has added more fuel to the ongoing debate what type of protection is suitable for genetic material relating to the human body. The debate has also been intensified with the completion of the Human Genome Project (HUGO) that when it ended in 2003 had identified nearly all of the genes in the human body. The findings of the project showed us that the human genome might be considerably more complex than first believed. When the project began, it was estimated that the number of genes in the human body were close to 100.000, today; the number has been revised, as it is believed that the actual number of genes are closer to 25.000.[3] This indicates that the human genome is more complicated than first thought, where a single gene may be involved in the production of ten- or twentyfold number of functional proteins.[4] At the same time, the limited number suggests that we

[1] Diamond v. Chakrabarty, 447 U.S. 303 (1980)
[2] Craig Ventner tried to patent a large number of so-called ESTs (expressed sequence tags). ESTs are gene fragments whose biological function, at least at the time, were unknown. This lead to opposition from leading academics who argued that since no utility was claimed it should not be eligible for patent. The question was specifically dealt with in the new utility guidelines issued by the USPTO in 2001, where the patent office explained that ESTs could be eligible for a patent provided that a specific, substantial and credible use could be described. For more information, see “The Great Gene Grab” p. 53 and the new utility guidelines issued by the USPTO p. 1094.
[3] http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml (2007-02-27)
[4] Who owns the human genome? What can ownership mean with respect to genes? Hubert Markl p. 516.

might face a tougher climate between competitors. With only 25.000 genes available, it might not be sufficient to enable a healthy competition between biotech companies, and it will be more important to be first on the patenting scene.

The findings have also caused opponents of absolute product patents, a protection that allows protection for all uses, whether they are disclosed in the patent claim or not, to argue that since the number of genes in the human body is finite, absolute product patents is not a suitable type of protection. The advocators of the limited purpose-bound protection point out that as it would be extremely hard, if not impossible, to invent around the patent, allowing absolute product patents would overcompensate the patent holder and run the risk of hamper research and make the medical care more expensive.

1.1 Purpose

The purpose of this thesis is to examine whether absolute product patents on human DNA sequences is a suitable type of protection. Should a patent holder be able to claim protection for utilities not described in the patent application or would it be preferable to limit the protection to the specific utility claimed in the patent application? The focus will be on comparing the absolute product patent with the most advocated alternative, the purpose-bound product patent, in trying to determine if the opposition to absolute product patents is well founded.

While the main purpose is to examine the suitability of product patents, an underlying issue is that the scope of protection given to patents may be too broad. As the type of protection is not the only factor in determining the strength of a patent, a deeper understanding of the patentability requirements is important as it explains how they may limit the scope of protection given to a patent.

In the first part of the thesis, I intend to explain why human DNA sequences are patentable and highlight the potential problems in meeting the patentability requirements. Patenting the human genome is not unquestioned and my aim here is to not only show that human DNA sequences are patentable, but also to present arguments opponents and proponents have in relation to the patentability requirements. This part will also explain how the interpretation of novelty, inventive step, industrial application and sufficient disclosure affect the strength of the patent.

In the second part of the thesis the intention is to examine the different types of protection available, focusing specifically on the product patents and purpose-bound product patent and why, or if, DNA sequences derived from humans should be treated differently from that of other chemical compounds. Arguments will be presented both in favour and against absolute product patents in order to help the understanding of the ongoing debate. The findings will be the basis for the conclusion.

1.2 Delimitations

As an overwhelming majority of biotech patents application in Europe is filed with the European Patent Organisation (EPO), the regulations in the European Patent Convention (EPC) are a natural starting point.[5] Although there may be referring to doctrine from countries bound by the EPC the aim is not to focus on any specific country bound by the convention, but to focus on the EPC itself and the case law from the EPO.

However, as the United States is one of the most influential countries in the worldwide patent community, an exclusion of their presence in this thesis is not desirable. Especially not seeing as the EPC and the United States patent system seem to move in the same direction, making the regulations more and more similar to each other.[6] Thus, where appropriate, important similarities and differences between the two patent systems will be highlighted; however, I do not make any claim to cover every aspect of the United States patent law.

What is said about the United States being one of the most influential patent countries in the world could to some extent be said about the Japanese patent system, along with the United States and the EPO, the Japanese Patent System forms an alliance that influence patent law worldwide. Unfortunately, there is not enough space to compare case law and regulations from Japan in this thesis.

The main object of this essay is to examine the patent system in relation to human DNA-sequences; this makes the question of the patentability of human stem cells fall outside the scope for this examination. In connection to scope of protection issues and their effect on research and innovation it is nearly inevitable to avoid questions regarding research exemptions and compulsory licenses, it is however not the intent to study the research exemption or compulsory license system other than on the surface to illustrate potential remedies to the negative downsides of an absolute product patent. In addition, issues relating to reach-through claims and product-by-process claims fall outside the scope for this thesis.

The field of patenting human DNA-sequences is in many ways controversial and the ethical and moral discussion has been intense for the last decade. While it is important to highlight potential dangers in patenting inventions relating to the human being this is not the main purpose for this thesis. In that aspect, this thesis might be considered more technical, excluding much

[5] Straus, J. Product patents on human DNA Sequences p. 67.

[6] As an example, the stricter utility guidelines issued in the US in 2001 raised the utility bar for patents on gene fragments, making it necessary to find a specific, substantial and credible use for the patent. Case law (see for example Opposite Division June 20, 2001, V28 seven transmembrane (V28 7TM) receptor/ICOS, O.J. EPO 2002 p. 293) from the EPO confirms that this also apply in Europe. Some also argues that the biotech directive makes it easier to obtain patents on DNA sequences in Europe, therefore, moving the EPC closer to the US patent law.

of the ethical discussion as there will not be sufficient space to introduce all ethical dilemmas related to the subject.

1.3 Method and material

I will primarily be using a traditional legal method, by examining the regulations relating to patent law in Europe I intend to present the background material needed in order to enable the reader to draw own conclusions. The most relevant convention will be the EPC, but case law from the EPO will be nearly equally as important as it shows how the EPC is supposed to be interpreted. The starting point for this thesis is the current EPC, however, a new revised EPC 2000 is supposed to enter into force on December 12, 2007, and to the extent there are changes that affect this thesis those changes will be highlighted. Other important sources include the Biotech Directive, doctrine from both the US and Europe and case law from the USPTO.

Although primarily using the traditional legal method I will also work with a comparative legal method when highlighting some of the differences and similarities in the US patent system when compared to the EPC. The comparative method also comes into place when comparing national practise that differs from the practise of the EPO.

When speaking of patenting the human genome it is important to remember that it is a field that is developing fast and it is not always that books are published as fast. However, in the days of the internet it has become easier to keep up to date and a considerable amount of articles have been collected from the internet and although some of them are an electronic version of the article published in an actual paper not all of them are. In cases where the information is only available online from a website or as a PDF-file it has been necessary to examine whom the author is and what kind of creditability the author possesses in order to give the reader as balanced view as possible.

There are some authors and works that have been more of an inspiration than others in the making of this thesis. In chapter four, this is the case with *From Clones to Claims* by Hans-Rainer Jaenichen et. al. Much of the inspiration in chapter five comes from Dr Sven Bostyn, to whom I owe many thanks for his excellent articles/books *Narrow trousers and narrow patents, a health risk? Product protection or purpose-bound protection for biotechnological inventions* and *Patenting DNA Sequences (polynucleotides) and scope of protection in the European Union – an Evaluation*.

1.4 Readers´ guide

In the second chapter, the basic nature of the DNA molecule and the gene will be introduced, the chapter will also cover the different ways we today make use of the gene, as well as a brief introduction to the HUGO-project.

The third chapter will introduce the patent system in general, providing the foundation for the discussion found in chapter five and in the conclusion. In addition to explain what is required in order to obtain a patent, it will explain the purpose of having a patent system along with the importance of providing the correct scope of protection.

The fourth chapter will deal with some of the more technical issues surrounding gene patents. Here, the patentability requirements will be introduced and more importantly, be placed in relation to human DNA sequences. The intent is to show why a human gene qualifies as patentable subject matter and some of the difficulties in meeting the patentability requirements. The chapter will also explain how the patentability threshold has been raised over the years since the first “patent on life” was granted, when patent offices around the world have been forced to react against overly broad claims. Finding the appropriate threshold has also limited many of the potential harmful effects an absolute product patent might have.

The fifth chapter will focus on the absolute product patent and the purpose-bound patent, explaining more in detail how the different types of patents work, and providing the arguments in favour and against the different types of protection.

Finally, the findings will be concluded in the conclusion.

2 What is DNA?

It is nearly impossible to understand the concept of what a gene is without introducing the DNA molecule. Although the basic nature of the gene was defined more than a century ago by a monk named Gregor Mendel it would take until 1944 to unfold the secrecy of the DNA molecule when Oswald Avery identified the DNA as the hereditary material. The development to our day has been astonishingly rapid. In 1953 the structure of DNA was established by James D. Watson and Francis Crick when they found out that DNA is a double helix, by that time, scientists already knew that one of the main function of the gene is that it codes for a protein. Today, nearly every gene in the human body has been mapped in the HUGO project, in what was claimed as a great success when it ended in 2003, two years earlier than expected.[7]

2.1 The HUGO Project

With the objective to make the human genome available to the public, work began in 1990 to try to identify all of the genes available in the human body. The project was coordinated by the United States Department of Energy and the National Institute of Health with the goal to complete the task within 15 years. Following rapid advances in gene sequencing the HUGO project would have no problems reaching their goals. In the year 2000 President Clinton of the United States and Prime Minister Tony Blair of the United Kingdom applauded the HUGO projects effort in a joint statement and in February 2001 the first draft of the human genome was completed and published in scientific magazines such as *Science* and *Nature*. Two years later, in April 2003, the project was declared to have reached its objectives.[8] The rapid development in DNA sequencing is however not the only reason why the project reached its goal quicker than expected. Following the success of the project, private owned companies saw their chance to profit on the research. In 1998, Celera Genomics announced that they would help out with the gene sequencing; they would however not make all of their findings freely available, as was one of the goals with the HUGO project. Rather, they would withhold some of the information in the wait for patent applications to be filed. Faced with the possibility that patents in private sector could destroy the objectives of the project, the HUGO project decided to increase the pace in order to reach their objectives earlier.[9] As time went

[7] Lewin, B. Genes. P. 3.

[8] See Bjornstad, D. An introduction to issues underlying patent policies for the emerging genetic information and medical treatment industry p. 3, 9. The joint statement by Clinton and Blair is available at http://clinton4.nara.gov/WH/New/html/20000315_2.html (2007-04-24). For more information about the HUGO project see http://www.ornl.gov/sci/techresources/Human_Genome/project/timeline.shtml (2007-05-02) that holds information about the goals of the project as well as a timeline allowing us to follow the development made over the 14 years the project went on.

[9] Bjornstad, D. An introduction to issues underlying patent policies for the emerging genetic information and medical treatment industry p. 8.

by, more and more companies became aware of the great potential that lies in patenting the human genome, and by the year 2000 investment made by public companies in research and development in the genomic field outnumbered the investment made by the government by approximately $1.8 billion.[10]

Thanks to the HUGO project we now know that the human genome consists of only around 25,000 genes in contrast to the 100,000 genes first believed. The number indicates that the genome is perhaps far more complicated than first thought, where the same gene might be able to perform many different tasks. The multi-functionality of the gene also gives a new dimension to the question whether or not absolute product patents should be allowed on the DNA sequence.[11]

2.2 Biotechnology

Although the usage of the term biotechnology did not occur until the 1970s, humankind has made use of biotechnology in many different ways for the last 5000 years, if not to breed plants then to make cheese. Throughout the 1970s the biotechnical field has undergone a rapid transformation as scientists today have the possibility to insert a specific DNA sequence into the gene of a plant or organism in order to develop a desired hybrid. More important in the aspect of patenting human DNA sequences and the scope for this thesis, biotechnology is used, not only to create new plants or genetically modified organisms, but also to develop new pharmaceuticals and in medical care to discover and treat genetic disorders.[12] With the rapid development in the field, the biotechnology industry has become a profitable field to enter not only for the private sector, but the public sector has also taken advantage of the possibility to protect their inventions in hopes that it might lead to commercial success. In the last decade of the 20th century, patent application rose 10,5 percent on biotechnological inventions yearly at the EPO, while the overall increase of all patents were just about 5 percent.[13]

2.3 The Genome

The genome could be said to be the very essence of life, not only does it control our appearances and the way we behave, it also controls our ability to stay healthy. Only recently, scientists at Oxford and Exeter claim to have found a new gene controlling obesity, and it is hoped that the discovery in

[10] Put in perspective, by the year 1993, government spending outnumbered that of public firms with about $88m, where the government spent $169m and public firms $81m. See Bjornstad, D. An introduction to issues underlying patent policies for the emerging genetic information and medical treatment industry p. 10.
[11] For further discussion on the multi-functionality of the gene and its influence on an absolute product patent, see chapter 5.
[12] Sterckx, S. Biotechnology, Patents and Morality p. 3.
[13] OECD p. 8.

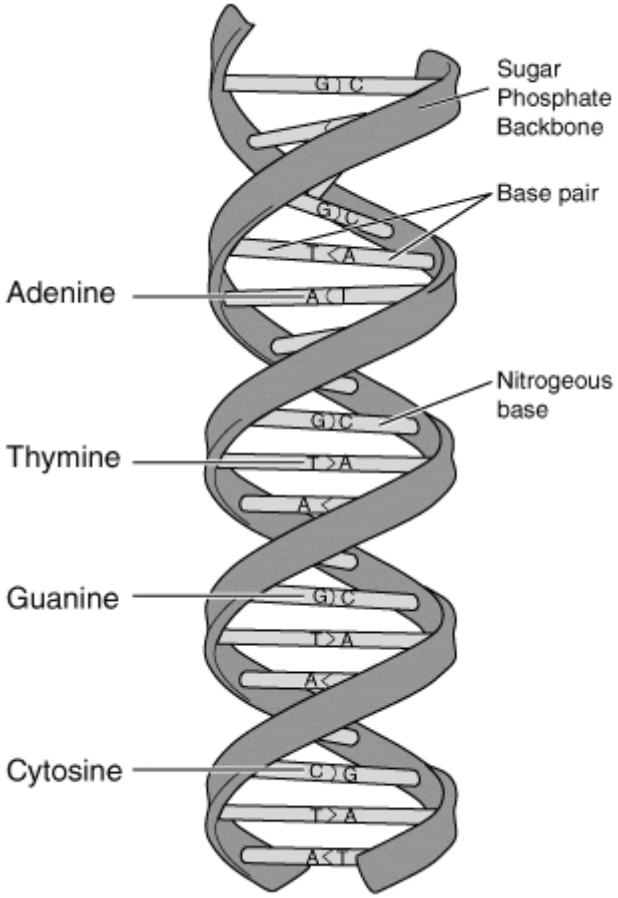
the near future can help people lose excess weight they carry just because of their genetic set-up.[14]

The genome exists in every living cell of every living organism and is a very long DNA molecule organised into units called chromosomes. During the 1920s, it was established that the human beings cells consisted of 48 chromosomes, a fact that was revised in 1956 when Joe Hin Tjio and Albert Levin could prove that the correct number of chromosomes were in fact only 46 organised into 23 pairs.[15]

The DNA molecule is a complex molecule resembling a ladder and is made up by thousands of sub-units called nucleotides, where each nucleotide consist of sugar, a phosphate group and a nitrogenous base. There are four nitrogenous bases: Adenine (A), Guanine (G), Cytosin (C) and Thymine (T), where A pairs with T and C pairs with G, these pairs are called complimentary pairs and always join in the same way. In the human genome there are approximately three billions base pair, while less complex organisms often holds less base pair, i.e. shorter genomes.[16]

One of the most important features of the gene is that it codes for proteins and for biopharmaceutical companies the genes ability to code for a specific protein is extremely valuable information. Proteins can be described as the working molecules of the cell and by isolating the gene it might be possible to find the protein for which it codes for. By knowing the function of the protein, the company might be able to manufacture the protein artificially and use it to produce medicine. This is the way we today manufacture for example insulin.[17] It is in the coding process for proteins that the nucleotides become useful. Nucleotides are combined in triplets where each triplet codes for one of the twenty amino acids available, as an example the triplet GCA, i.e. three nucleotide next to each other containing the nitrogenous bases G, C and A, codes for the amino acid alanine. Considering that the genome holds three billions base pairs, many different amino acids will be coded for, and when the correct combinations of coded amino acids occur, they in turn will code for a protein. It is believed that the different combinations of amino acids may express 100,000 proteins.[18]

[14] See "The Daily Telegraph" from Friday, April 13, 2007 for more information of the so-called FTO gene.
[15] Conley, J. Rethinking the product of nature doctrine. p. 8.
[16] Ibid. p. 8.
[17] SOU 2006:70 p. 93.
[18] Ibid. p. 46. See also Scherer, M. The economics of Human Gene Patents p. 1348.

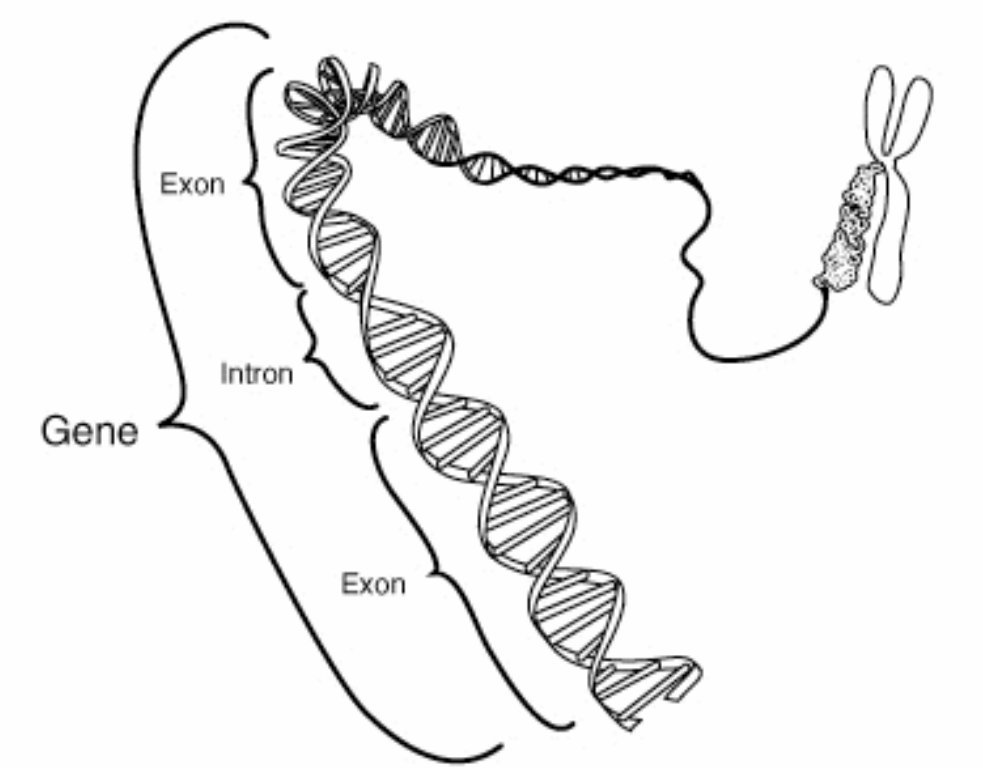


The illustration shows a double helix DNA sequence with the complimentary base pairs.[19]

However, not the entire DNA sequence is involved in coding for proteins, in fact, less than ten percent of the DNA consists of genes. The remaining 90 percent is non-coding introns. Until recently scientists saw no use in the introns and labelled them as junk-DNA, but as research continued, their position had to be reviewed as new uses for the introns continues to be discovered. The coding counterpart is known as exons. Unlike the exons, the introns vary widely among species and even among individuals of the same species, making every individual unique. For researchers interested to make use of the DNA sequence, these introns often makes the DNA sequence more difficult to work with as they make the sequence longer, and since introns are of no use in the coding process researchers strive to remove them in the artificial production of the DNA sequence. What is left, i.e. the DNA sequence without the non-coding introns, is called cDNA. As a result, the isolated gene will no longer be an exact replication of the sequence

[19] Picture available at: http://www.genome.gov/Pages/Hyperion/DIR/VIP/Glossary/Illustration/dna.cfm?key=deoxyribonucleic%20acid%20%28dna%29 (2007-05-07) The picture was created by the National Institute for Health and according to the same website *´All of the illustrations in the Talking Glossary of Genetics are freely available and may be used without special permission.*`.

available in the human body, since cDNA is not available without human intervention.[20]



The illustration shows the gene with the non-coding introns and the coding exons. Seen on the right is the chromosome. [21]

2.4 The use of human genes today

In patent applications, DNA sequences are claimed for many different purposes. Thanks to the HUGO-project most of the human genome is known, but the impact of the project also means that it has become increasingly unusual in recent time to find "new" genes. Therefore most of the research today aims to find new applications and functions of a known gene or new uses in diagnostics methods.[22]

2.4.1 Diagnostic Testing and Gene Therapy

In modern day, the use of the gene is not limited to discover the structure of proteins and artificially manufacture them. With our knowledge through mapping nearly all of the human genome, we have learnt the structure of how the genome is supposed to look. By knowing the structure of the gene it might be possible to discover mutation in a gene in the human body and by

[20] Conley, J. Rethinking the product of nature doctrine. p. 10.
[21] Picture available at: http://www.genome.gov/Pages/Hyperion/DIR/VIP/Glossary/Illustration/gene.cfm?key=gene (2007-05-07). The picture was created by the National Institute for Health and according to the same website *´All of the illustrations in the Talking Glossary of Genetics are freely available and may be used without special permission.`*.
[22] Bostyn, S. Narrow trousers and narrow patents, a Health risk?

finding the faulty gene it is often possible to diagnose the disease as well.[23] This is called diagnostic testing and one of the best examples of patents for this purpose is the gene BRCA1 used to discover breast cancer. The BRCA1 patent has been a commercial success, but the patent has also been heavily criticised not only by competitors but also by leading experts because of the broad scope given to the patent, where concerns were raised that it would be more difficult to get access to the patented information.[24] Little did it help that the owner of the patent, Myriad Genetics, decided to exercise their rights in the strictest way possible, by only allowing the tests for BRCA1 to be performed by their own laboratories or a few licensed laboratories, making the prices for the tests considerably higher. As a result, the patent was challenged and eventually the EPO decided to revoke the first BRCA1 patent for the lack of novelty.[25]

If it is possible to locate the faulty gene, it might also be possible to replace it with a normally functional gene with the goal to produce the protein the patient might lack. Using the gene for this purpose is known as gene therapy. Unfortunately, the development of the field is still in its early stages and the progress in research has been slow, not least because many diseases involve mutations in several different genes. What is clear is that gene therapy holds a great deal of potential and scientists seem to be optimistic about the possibilities in the field, especially where the disease relates to an error in a single gene, a so-called monogenic disease.[26]

2.4.2 Research tools

Another possibility is to claim the gene as a research tool, where the gene is used to develop a commercial product, such as medicine or a vaccine. The research tool itself, i.e. the DNA sequence, is not meant to be the end product but rather a helpful tool to promote new inventions. These research tools may comprise an entire gene, but more often they only relate to gene fragments or in some cases only a few base pairs. It is under this category that ESTs or SNPs often belongs, whose patentability has been and is being subject of a rancorous debate. ESTs and SNPs are gene fragment whose utility often is unknown and are used to locate genes associated with specific diseases.[27] Although opponents to patents on gene fragments admits that there is a potential in ESTs and SNPs they do not agree on reserving an unexplored research area to a patent holder, where it is not possible to show a credible use for the gene fragment. As we shall be aware of later in chapter 4, the patent offices have raised the patentability threshold, and albeit not excluded the patentability of ESTs and SNPs, the patentee must show a

[23] Nuffield Council on Bioethics, The ethics of patenting DNA p. 47.
[24] Bostyn, S. A test too far? A Critical Analysis of the (non)-patentability of Diagnostic Methods and consequences for BRCA1 Gene Type Patents in Europe.
[25] Matthijs, G. Patenting genes: May slow down innovation and delay availability of cheaper genetic tests, p. 1359.
[26] Nuffield p. 47, see also Patenting Human Genes, a report from the Danish council of ethics, p. 38.
[27] Nuffield p. 47, see also Patenting Human Genes, a report from the Danish council of ethics, p. 56.

substantial, credible and specific use in the patent claim in order to obtain a patent.[28]

Originally, companies showed strong interest in research tools due to the commercial potentials the possible finished product has. While it is true that research tools holds a commercial potential for the companies to exploit, a consequence of this was that patents were filed in very early stages, often before knowing the exact function of the patented product, to ensure that they would be able to continue their research. As a result of granting a patent in that early stage where no function is known, it excludes competitors from further research in the field. Even though recent studies show that while the biotechnology companies seems to have stronger interest in research tools than the public sector, the interest in research tools may be diminishing. This is thought to be a consequence of the patent offices attempt to raise the threshold for patentability to avoid the speculative claims that permeated the field in the early ages of DNA patenting.[29]

2.4.3 Therapeutic Proteins

If the interest in research tools may be diminishing, the industry shows continued strong belief in the patenting of therapeutic proteins.[30] By identifying and isolating the structure of the gene, scientists have the possibility to artificially produce the protein for which the gene encodes. In many cases, this protein can be used to develop new medicines and vaccines, for example growth hormone and insulin. In other words, therapeutic proteins are produced directly from the DNA sequence and have been developed into medicines.[31] As you can imagine, the market for using therapeutic proteins to develop new medicines is economically very lucrative, where the market already today is significant.[32]

[28] Decision of the Opposition Division, Official Journal of the EPO, 6/2002, (2002), pp. 293–308.
[29] Hopkins, M. The Patenting of Human DNA: Global trends in Public and Private Sector Activity p. 37.
[30] Ibid. p. 37.
[31] Nuffield Council on Bioethics, The ethics of patenting DNA p. 73.
[32] Ibid. p. 5.

3 The Patent System

The patent system is the legal instrument chosen by the legislator to ensure that researchers and investors have the incentives to continue research in an unexplored area. Nevertheless, while it in the patent system lies the important factor that it gives incentives for research and development; if the system is not used properly the result might as well be opposite. Therefore, it is of the essence to find the appropriate balance between providing inspiration and causing anti-competitive effects.[33]

The aim for this section is to explain how the patent system works by first introducing what is required in order to obtain a patent at the EPO. To enhance the understanding of the forthcoming discussion, the latter parts of this section focuses on the purposes of the patent system and the importance of finding the correct balance between a narrow and broad scope of protection and the consequences should the right balance not be found.

3.1 The European Patent Convention

While work has begun to harmonise the patent laws within the European Community with the ambition to make Europe a more competitive market in relation to the American patent system, there is still a long way to go before a community patent is agreed upon. Meanwhile, the best way today to seek patent protection, especially if the company seeks protection in more than one European country, is still with the EPO. When the EPC entered into force in 1977, the aim was to make the patent procedure less time consuming by centralising the procedure, but the main purpose was to make it less expensive to apply for a patent. Although the cost of obtaining a patent with the EPC still involves considerable amounts of money, the EPC now seems to be the preferable system for companies to go through in order to protect their inventions.[34]

The EPC enables the applicant to receive patent protection in more than one country with just one application. When applying for a patent at the EPO, the applicant designates the countries where he wants the patent to be valid. If granted, the patent will be given the same protection in those countries as a patent granted by the national patent offices.[35]

3.2 The Biotech Directive

Although the community patent has not yet been agreed upon, the attempts to harmonise the patent laws within the European Union have had some success when the Biotech Directive was finally decided upon in the mid-

[33] Thumm, N. Patents for genetic inventions p. 1411.
[34] Levin, M, Immaterialrätt p. 206
[35] Ibid. p. 49.

nineties. It had become increasingly obvious during the 1980s that the European Union had to try to harmonise the field of biotechnical inventions and eventually, ten years after the first draft, in May 1998 the European Parliament adopted the Directive on Biotechnology patents.[36] The Biotech Directive was met with mixed emotions from the member states; the Netherlands objected to the Directive by bringing the European Parliament and the Council before the Court of Justice of the European Communities and demanded that the Directive should be declared void.[37] The claim was rejected by the court and by 30 July 2000 all member states should have implemented the Directive. However, it would take until 2006 for all member states to implement the Directive, when Luxemburg became the last country to do so.[38]

Although the Directive demands that the member states implement the regulations in national law, the same does not apply for the EPO. The EPC may only be changed by a diplomatic conference of the contracting states; however, since nearly all members of the EPC are also members of the European Union it would be difficult for the EPO to completely disregard the Directive. Neither would it be in the interest of the EPO to have regulations that make it less attractive to seek patent protection with the EPC than applying for a patent in a national patent system. Consequently, in 1999, a new chapter entitled Biotechnological inventions was amended in the Implementing Regulations of the EPC containing four new rules in accordance with the Biotech Directive. [39]

3.3 Patentable subject matter

In order to obtain protection for an invention it must qualify as patentable subject matter. In the EPC, as well as in most countries patent law, there are three basic patentability requirements that have to be met: the claimed invention must be novel, involve an inventive step and be susceptible for industrial application. In addition to the basic requirements the invention must also qualify as just an invention, i.e. a mere discovery is excluded from patentability. Furthermore, the invention must also be disclosed in the patent application in a sufficient manner to enable the skilled person to reproduce the invention.

The new chapter entitled Biotechnological inventions that was amended into the EPC in the light of the Biotech Directive, now also provides us with additional information about what is patentable in relation to biotechnological inventions. Rule 23(d) deals with exceptions to patentability, explaining that processes for cloning human beings are excluding from patentability, while rule 23(e) says that the human body at

[36] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.
[37] Sterckx, S. Biotechnology, Patents and Morality p. 39.
[38] http://www.wptn.com/Mailing/Feb_2007_4/details/patents/divergent.html (2007-04-06) see also SOU 2006:70 p. 175.
[39] Sterckx, S. Biotechnology, Patents and Morality p. 39.

its various stages and the simple discovery of one of its elements cannot constitute patentable inventions.

Partly because the complicated nature of the patentability requirements, but also to make the thesis more understandable for the reader I have chosen to leave a more detailed description of the requirements to the next chapter where I will examine why DNA sequences are patentable and how the patentability requirements affect the scope of protection given to the invention.

3.4 Different types of patents

There are essentially three categories of patents; product patents, process patents and use patents. The product patent is a patent on the substance per se, whereas process patents and use patents allows the inventor protection for a certain method or in the latter case a particular use disclosed in the patent claim.[40] Although a product patent cover all uses of the patented invention it should be noted that a patent on the substance per se does not exclude others from claiming new uses of the invention. These patents will however be dependent patents and the use of dependent patents relies on the possibility for the patentee to obtain a license from the original patent holder.[41]

When applying for a patent it is important to distinguish between the patent claims and the description of the invention. While the description is meant for the skilled man in the art to enable him to reproduce the invention, the claims define the scope of protection.[42] It is also the claims that determine what type of protection the patent is given. If the claim is limited to a certain method or use, that patent will be a process patent or a use patent. Should the claim hold no specification of the use or method, but just claiming the substance, the claim will be a product claim.[43] It should however be noted that the description may to some extent be used to define the scope of protection. According to article 69 EPC the extent of the patent protection shall be determined by the terms of the claims. Nevertheless, in order to harmonise the different views in determining the scope, mainly between Germany and the United Kingdom, article 69 has an attached protocol according to which the extent of protection should not be strict literal of the wording used in the claim, but neither should the claims serve as just a guideline. This means that circumstances mentioned in the description may be taken into account when determining the actual scope of protection. This way of interpreting the claims is referred to as the doctrine of equivalence and means that the scope of protection actually covers not only the literal

[40] Nuffield p. 24.
[41] Ibid. p. 31-32.
[42] Radder H. Exploiting Abstract possibilities: A critique of the concept and practice of Product patenting p. 280.
[43] Paterson, G. The European Patent System, p. 340-341.

wording of the claim, but also improved inventions that are equivalent with the patented invention.[44]

Although it is not required to include a specific purpose of the invention in the patent claim when the claim relates to an invention per se, in the field of biotechnology it is however required by the inventor to disclose one way to make use of the invention in some kind of industry. This is due to the special regulations following the Biotech Directive. While there has been significant debate in the light of the Biotech Directive whether it is now required to include that use in the claims, until the matter is clarified by the Commission or the EPO, the disclosure of the industrial application requirement is most likely to be met just by including the use in the application.[45]

3.5 The purpose of a patent system

The patent system could be said to give an inventor a legal monopoly for a certain number of years in exchange for the disclosure of the invention. Not only does it allow the inventor the possibility to recoup his expenses during that period, it also gives the inventor the chance to profit from licensing fees, should the inventor be able to license his product.[46] However, the reason for a patent system is not to reward certain people with legal monopolies, although admittedly that is one of the consequences of the system. Rather, the system is designed to benefit the society as a whole by exposing the information to the public domain, making it possible for others to continue to develop the invention rather than having to throw away resources to re-invent that invention. As the Romans would say: *facile est inventis addere*, it is easy to add to things already invented.[47]

The possibility to recoup expenses is an extremely valuable factor in the biotechnology sector, where intangible resources often proves to be the only valuable resource of the company and patents have come to play a huge part in the developing of new biopharmaceuticals.[48] It is estimated that it will take ten years in order for a pharmaceutical to complete the regulatory process, and while every pharmaceutical has a developing cost, what is more worrying for biotechnology companies is that only about one in ten pharmaceuticals eventually reach the consumer market. In the end, it is believed that the cost of bringing a pharmaceutical to the market is approximately £350m.[49] Even with the protection of the patent system, the

[44] Levin, M. Immaterialrätt p. 285-286. The United Kingdom is more in favour of interpreting the scope from the strict literal meaning of the claims, whereas Germany favours the principle that the claims should only serve as guidelines for the scope of protection.
[45] A more detailed discussion about the Commissions intent will follow when examining the industrial application requirement.
[46] Bostyn, Patenting DNA sequences p 11.
[47] Sterckx, S. Biotechnology, Patents and Morality p. 25.
[48] Thumm, N. Patents for genetic inventios: a tool to promote technological advance or a limitation for upstream inventions? p. 1416.
[49] Toumi, E. In defence of gene patents p. 135.

huge estimated development cost is often sufficient to deter companies to continue or take up research in an unexplored field, but without the patent protection, we would undoubtedly see far less activity in the private sector than we do today. Therefore, the patent system is important as it helps to spur inspiration. Knowing that a patent protection is available, private companies will be given incentives to pursue research, whereas without the protection it would give no incentives for the private sector to conduct research, as it would be easier and cheaper to "free ride" on the research of others.[50] It is also evident that without the available protection healthcare would not have reached the level we see today. On the other hand, the patent system does impose a higher price on the healthcare. Therefore, it is important to find a proper balance in the scope of protection.[51]

However, the patent system does not only provide incentives for companies to conduct further research. With the disclosure of a patent, the invention will become publicly available and by that, it teaches the world how to make the invention. Consequently, the patent system provides incentives for the inventor not to keep the invention secret. If the inventor should decide not to disclose the information about the invention, that information could stay out of the public indefinitely. As a result, if the invention becomes a trade secret, it would lead to the total opposite of what the patent system strives to achieve. The secrecy would force competitors to invest money on duplicated development, and although the biotechnology field as well as any field is the object for reverse engineering, it would still demand unnecessary resources in order to reach a conclusion that would be freely available should the invention be protected by a patent.[52]

3.6 The importance of finding the right scope

The scope of protection is mainly determined by the claims made in the application as they define and limit the protection obtained by the patentee. Understandably, the inventor wants as much protection as possible and in most cases, the first claim will be very broad, claiming everything that is possible in relation to the invention. Of course, the inventors view is not often shared by the patent offices, and most certainly not by the competitors. The final scope will be a delicate balance act between the view of the inventor and the patent office, where the patent office has to take into account the inventor's right to compensation and weighs it against the social cost of providing a legal monopoly. As a final remedy, the competitors have the right to challenge the patent in court or via the patent office, in what could be a lengthy and costly process.[53]

[50] Bjornstad, D. An introduction to issues underlying patent policies for the emerging genetic information and medical treatment industry p. 12.
[51] Bostyn, S. Patenting DNA sequences and the scope of protection p 126.
[52] Toumi, E. In defence of gene patents p. 136.
[53] SOU 2006:70, p. 22.

Finding the right balance between a narrow and a broad scope is crucial for the patent offices and it is not always an easy task to accomplish. If the scope is too narrow it will result in that inventions with only minor variations of a patented invention can be produced without infringing the patent. While it means that a narrow patent encourages competition after the original invention, the effect might also be that fewer companies will enter the market to try to make that pioneer invention. Since the patent holder has invested heavily in developing the patented invention, knowing that only a narrow scope is available might deter him from developing the product in the first place as it would be more profitable to free ride on the research of others. Granting patents with too narrow scopes will therefore be an inhibiting factor on future research as it does not allow the inventor to recoup the expenses. While it is true that the most important benefit by providing a narrow scope is that it inspires inventors to try to improve the invention, the potential downside is that by not being given sufficient protection it encourages the original inventor to keep the invention secret. Although the inventor could be able to enjoy some kind of protection by protecting the invention as a trade secret, the society will suffer as an effect. Just as the result of having no patent protection at all, mentioned in the previous section, the result of a narrow scope will be that competitors invest money to invent something already invented [54]

Providing a broad patent will make it possible to avoid the problem where the inventor chooses to keep his discoveries for himself. Knowing that a broad scope is available makes the inventor less inclined to keep the invention secret as the patent system will provide adequate protection should he choose to make the invention publicly available. However, allowing a scope that is unsatisfactory broad might nevertheless have the same effect as a narrow, in the sense that it might lead to a decrease in technological development. If the competitor, on the one hand, runs the risk of litigation for patent infringement because the outer boundaries of the broad patents are not clear, and on the other, will be dependent on someone else's patent, he will have no interest to invest heavily in the field.[55]

One of the biggest problems with the broad scope is that the first inventor to obtain a patent will be overcompensated. The situation will lead to a winner takes it all-scenario, where the first inventor receive everything and the competitors research is likely to be non-profitable. Hence, the competitors will most likely think twice before committing themselves to the field, as it is not cost-effective placing considerable amounts of money on an investment if there is a good chance that someone else is further ahead in their research, and by that run the risk of not obtaining protection for the research.[56]

[54] Bostyn, S. Patenting DNA Sequences and scope of protection, p. 24.
[55] Sterckx, S. Biotechnology, Patents and Morality, p. 25.
[56] Bostyn. S. Narrow trousers and narrow patents, a health risk?

4 Patentability of Genetic Materials

Although patents on human DNA sequences have been allowed for several decades now, a number of commentators still argue that inventions relating to the human genome should not be eligible for patents, as human DNA sequences cannot meet the requirements for patentability. The purpose of this chapter is to present how the general criteria of patentability with the intent to show how the patentability requirements work in relation to patents on human genes. However, before focusing on the patentability requirements the distinction between a discovery and an invention shall be introduced. Before the end of this chapter, the aim is to explain how the patentability requirements can be useful to limit the potential harmful effects an absolute product patent might provide.

4.1 Discovery or invention?

Not all of the opponents to gene patents are opposed to the patenting of the human genome on ethical grounds. It is often argued by opponents to gene patents that the elements isolated from the human body should not be eligible for a patent, as they can never be invented; only discovered. Some people go as far as saying that what really are being patented are not useful molecules but rather basic scientific findings.[57] These opponents base their objection on article 52 in the EPC that requires the patented material to be an invention, as a discovery is not eligible for a patent. Normally, the distinction between a discovery and an invention is not that difficult to distinguish, however, in the field of biotechnology, the distinction has become harder to define as it is not always easy to see how a gene already available in the human body can qualify as an invention rather than as a discovery.

4.1.1 The Product of Nature Doctrine

The way the EPC has chosen to solve the issue has been greatly influenced by the way the United States Patent office (USPTO) has decided to deal with the matter. In the United States, the statute[58] makes no distinction between an invention and a discovery, leading to believe that every discovery is patentable. This is however not the case. In doctrine, but mainly in case law, the concept of product of nature started to develop in the early stages of patenting biotechnological materials. The United States Supreme Court has made a distinction between discoveries from human intervention

[57] Sterckx, S. Biotechnology, Patents and Morality p. 226. See also Scherer, F. The economics of Human Gene Patents, p. 1354.
[58] See 35 U.S.C. section § 101.

and products of nature, and taken the position that whereas product of nature are excluded from patentability, products derived from nature are not.[59]

In the landmark decision Diamond v. Chakrabarty, Chakrabarty claimed a bacterium, genetically engineered to break down oil. The USPTO rejected the claim on the grounds that the bacterium was a naturally occurring substance and could as such not be patented. Chakrabarty appealed the ruling and eventually the United States Supreme Court decided to review the case.[60] In its decision, the United States Supreme Court held that a live human-made micro-organism is patentable subject matter under 35 U.S.C. §101, thus paving the way for microbiological inventions to be patentable. To this day this is the only case in biotechnology to be decided by the United States Supreme Court, and although the outcome was a mere 5-4 decision in favour for Chakrabarty it is one of the most cited and important case in this field. Its importance is not exclusive for the United States but the case has greatly influenced the distinction between a discovery and an invention worldwide, not least in Europe.[61]

4.1.2 Discovery or invention according to the EPC

It should be clear from the outset that while a discovery, unlike the provisions in the United States, is excluded from patentability, there is still a high resemblance between the USPTO and the EPO in the way that they deal with the problem.[62] The issue is addressed in the Guidelines for examination in the European Patent Office issued by the EPO which states that a previously unrecognised substance occurring in nature is a mere discovery and does not constitute a patentable invention. However, if the gene is isolated from its natural surroundings it is not a case of merely finding something freely occurring in nature. The reason is that nature alone is not capable of producing the gene outside the human body.[63] This position has also been confirmed by EPO in *Relaxin*, where the Technical Board concluded that if the DNA sequence is isolated from its surroundings and could be properly characterised, the substance per se could be patentable, even if it in its natural state is freely occurring in nature.[64]

[59] Bostyn, S. Patenting DNA sequences and Scope of Protection p. 15.
[60] Bjornstad, D. An introduction to issues underlying patent policies for the emerging genetic information and medical treatment industry p. 15.
[61] Conley, J. Rethinking the product of nature doctrine. p. 22.
[62] See article 52 (2) EPC that expressly excludes discoveries from being regarded as an invention.
[63] Guidelines for Examination in the European Union Part C, Chapter IV, 2a.2 rule 23c(a).
[64] Opposite Division, ”RELAXIN” EP-B1 112 149, OJ EPO 1995, 388, later confirmed by the Technical Board in T 272/95 ”Relaxin/HOWARD FLOREY INSTITUTE”. The case is available at http://legal.european-patent-office.org/dg3/pdf/t950272eu2.pdf (2007-05-21).

4.2 DNA sequences and the patentability requirements

The discussion of whether the product qualifies as an invention or a discovery should not be confused with the discussion whether the claimed invention meets the patentability requirements or not. Just because a DNA sequence qualifies as an invention does not mean that a patent automatically will be granted. The invention will also have to meet the patentability requirements, namely, novelty, inventive step and industrial application in order to be patentable, in what will often prove to be a much tougher task than meeting the requirement to qualify as an invention.

4.2.1 Novelty

The first of the three patentability requirements requires that the compound is novel, that is, the compound cannot be known anywhere in the world prior to the claim. The legal basis is found in article 54 in the EPC and although there are some exceptions to the novelty requirement in article 55 EPC, to be safe, the inventor should not disclose his invention in any way prior to the patent application. In this aspect, the novelty criterion is absolute, it is irrelevant in which language the information is made available; any previous description will destroy the novelty value no matter wherever in the world the information is found or whenever it is published.[65] Thus, even discloses made by the inventor himself can destroy the novelty value, should the information not be protected by a confidentiality agreement. In contrast, the provisions in the United States and Japanese patent law permits a grace period, allowing the inventor to use his invention for a limited time without it affecting the novelty value.[66] In worst cases the absence of a grace period in Europe can lead to that even if a patent is granted in the United States, protection cannot be obtained in Europe as disclosures made by the inventor has destroyed the novelty value.

The decisive moment when determining the novelty value is what constituted state of the art prior to the filing date. In the event that two inventors apply for a patent on the same invention, the EPO follows the "first-to-file"-principle, meaning that the application with the earliest filing date will prevail. The United States patent system differs from the approach taken by the EPO, by taking a "first-to-invent"-approach that strives to give the original inventor the right to ownership to the invention even if the original inventor was not the first to claim the invention. The different approaches both have their advantages and disadvantages. While a "first-to-

[65] The European Patent System p. 485-486. This is in contrast to patent law in the United Kingdom, where publications more than 50 years old cannot be taken into account for novelty purposes (see 1949 UK patent Act section 50(1)).

[66] There is a continuous debate whether or not a grace period should be introduced in the EPC but as it is now, no decision has yet been made. For further reading see "The introduction of a grace period in European patent law" available at http://www.european-patent-office.org/news/pressrel/pdf/galama.pdf (2007-04-25).

file"-approach makes it easier to determine who has the right to the patent, the approach may seem unfair as it can result in that the rightful inventor will not receive the compensation he feels entitled to.[67]

4.2.1.1 Novelty and DNA Sequences

It is important to point out that the human genome is not considered available in terms of patent law just because it exists in the human cells. What is being claimed is not the same DNA sequence that occurs in nature, but an isolated DNA sequence coding for a protein.[68] In the view of patent law, in cases where the patent claim relates to a cDNA sequence, i.e. where the non-coding introns have been removed, a known DNA sequence is not novelty destructive over the cDNA sequence, since cDNA does not occur in nature and is not available without human intervention.[69]

A landmark decision regarding the novelty value in DNA sequences is *Relaxin*[70] where the patentee claimed an isolated cDNA fragment encoding human H2-preprorelaxin. As well as being challenged on the grounds that the claim was not an invention, it was also challenged on the grounds that there could be no novelty value in isolating a gene already present in the human female body. In its decision, the Opposite Division concluded that *"it is established patent practise to acknowledge novelty for a natural substance that has been isolated for the first time and which had no previously recognised existence."*[71] Since the isolated cDNA encoding H2-relaxin was unknown before the inventor disclosed the invention, the Opposite Division held that the claimed sequence had novelty value. The case is a confirmation of the principle that a natural substance isolated for the first time does not lack novelty value just because it already exists in nature.[72]

4.2.1.2 Difficulties in meeting the requirement

In relation to gene sequences, the requirement of novelty does not present many problems, as DNA sequences that have been prepared for the first time will often meet the novelty requirement.[73]. However, during the last couple of years one big issue has grown in importance in the light of the completion of the HUGO project. Ever since the first draft in 2001, the HUGO-project has provided the public with information about an enormous amount of genetic material. However, with the publishing of these results it also means that most of the human genome has been mapped and is publicly available. With this in mind, it might be hard to see how an isolated DNA sequence can be novel when it is available in a DNA library. A similar issue

[67] OECD p. 26.
[68] Bostyn, S. Patenting DNA sequences and Scope of Protection p. 44.
[69] T1112/96"Erythropoietin production/GENETICS INSTITUTE", EP-B1 205 564.
[70] Opposition Division, Relaxin and T272/95 Relaxin/HOWARD FLOREY INSTITUTE, EP-B1 112 149, OJ EPO 1995, 388. The case is also referred to under the section "Discovery or invention?".
[71] Jaenichen, H-R. From Clones to Claims p. 420-421.
[72] Examination Guidelines for patent Applications relating to Biotechnological Inventions in the UK Intellectual Property Office p. 7.
[73] Bostyn, S. Patenting DNA sequences and Scope of Protection p. 44.

was dealt with in T301/87[74] where the DNA sequence claimed by the patentee was already available in a DNA bank. The Technical Board held that the inclusion of a DNA sequence in a DNA library does not give the person skilled in the art any indication of the isolated DNA sequence, "*thus, the idea that the gene bank itself would once for all anticipate an invention relating to a nucleotide sequence which may be contained therein somewhere, cannot be sustained*".[75] Although the principle was confirmed once again in T412/93[76], it is believed that because of the HUGO project, and in the view of an increasing use of computers to retrieve DNA sequences, that much of the human genome will be regarded as known and under such circumstances, no patents on the sequence per se can be allowed.[77]

4.2.2 Inventive step

Once the novelty requirement has been met, it is required by article 52(1) EPC that the invention involves an inventive step. While the assessment of the novelty requirement attempts to decide if the claimed invention differs from the state of the art, the inventive step requirement decides whether there is a leap in technology between the two inventions. The requirement is met if the invention, having regard to the state of the art, is not obvious to a person skilled in the art. The concept of non-obvious means that if the person skilled in the art could modify the existing state of the art and arrive at an invention that falls within the terms of the claim, the invention will fail the inventive step, i.e. if the claimed invention follows plainly from the prior art, it is not possible to obtain a patent.[78]

The person skilled in the art is a common denominator for the assessment of novelty, inventive step and disclosure requirement, and it is the same degree of skill required by the person skilled in the art in all three categories.[79] In the area of biotechnology, the Technical Board has given a rather precise definition of the person skilled in the art by explaining that the person should not hold the knowledge of a Nobel Prize laureate, but still be a highly skilled laboratory technician.[80]

4.2.2.1 Inventive step and DNA Sequences

As an effect of the improved ways to sequence and process genes, it has gradually become a more difficult task to meet the requirement for inventive step. Unlike in the United States, where structural non-obviousness of the claimed molecule is sufficient to grant inventive step, a structural non-

[74] T301/87, "Alpha-interferons/BIOGEN", EP-B32-134, OJ EPO 1990, 335.
[75] The case can be found at http://legal.european-patent-office.org/dg3/biblio/t870301ex1.htm#txt (2007-05-21) and the quotation under paragraph 5.8.
[76] T412/93 "Erythropoietin/AMGEN" EP-B1 148 605.
[77] SOU 2006:70 p. 187. See also Bostyn, S. Patenting DNA sequences and Scope of Protection p. 46.
[78] See article 56 EPC and EPO:s Guidelines for examination Part C chapter IV section 9.4.
[79] See T158/91, see also Jaenichen, H. From Clones to Claims p. 50.
[80] See T60/89 and T223/92.

obviousness argument alone will not be successful at the EPO, at least not where the DNA sequence is isolated according to conventional methods.[81] Instead, more is required by the inventor in order to meet the inventive step, for instance, inventive step may be acknowledged where the end-product shows surprising and unexpected features or if an inventive method was required to isolate the DNA sequence.[82]

It is getting more unusual by the year to find a completely "new" gene, a fact that is supported by statistics showing a decline in the amount of patents granted on human DNA sequences per se. Instead, many believe that future patents will be different from the patents claiming the gene sequence per se. Rather than being *the* invention, the DNA sequence in many future applications will probably be *part of the* invention. In these cases, the inventive effort will no longer be to isolate the gene, but rather trying to find the function of the gene.[83]

4.2.2.2 Difficulties in meeting the requirement

Unlike the United States, where nearly every novel DNA sequence qualifies as inventive due to the appliance of the structural non-obviousness argument, the patenting threshold in Europe is considerably higher. Due to advances is DNA sequencing it is questionable whether DNA sequences obtained with ordinary cloning processes will be able to qualify as inventive. Often, in order to fulfil the requirement, it is required to show unexpected effects in the end-product or difficulties in the isolation procedure.[84]

A potential obstacle of the inventive step relates to the ever-increasing knowledge of our heritage. During the last two decades, we have learnt that the human genome has much higher similarities with other species than first thought. Just to name one example, the human being shares around 98 percent of its gene with the chimpanzee.[85] This means that the structure of an animal gene will often be represented in the human body. The implications on the inventive step might be that with the knowledge of the DNA sequence found in another specie render the human gene obvious, thus not being able to meet the inventive step requirement.[86] In a fairly recent case, the Technical Board of appeal held a specified human gene sequence

[81] Jaenichen, H-R. From Clones to Claims p. 509. For American legislation and the focusing on the structure of the DNA sequence, see In Re Bell 991 F.2d 781 (Fed. Cir. 1993), for further reading about American case law on inventive step, see also In Re Duell 51 F.3d 1552 (Fed. Cir. 1995), that explains that the knowledge of the protein the particular DNA molecule encodes does not render the DNA molecule itself obvious.
[82] Jaenichen, H-R. From Clones to Claims p. 510, 515.
[83] Hopkins, M. The Patenting of human DNA: Global trends in Public and Private sector Activity (the PATGEN Project) p. 37.
[84] Nelson, A. Obviousness or Inventive Step as Applied to Nucleic Acid Molecules: A Global Perspective, p.31.
[85] Put in perspective, the chimpanzee only shares 97 percent of its gene with the gorilla, making the chimpanzee genetically more similar to the human being than the gorilla, see Ridley, M. Genom. P. 36. The human being also shares around 50 percent of its genes with a banana, see Danish Council of Ethics, Patenting human genes and stem cells p. 69.
[86] Soames, C. Inventive step and genomics, p. 729.

to be obvious since it was to 78 percent identical to a known mouse sequence and the sequence had been retrieved in a straightforward manner, indicating that, in the future, we might face a higher threshold in meeting the inventive step.[87] Some believe that the knowledge of human genes counterparts in an animal might implicate that lesser product per se patents will be granted as it will be hard to meet the novelty and inventive step requirement.[88]

4.2.3 Industrial application

The industrial application requirement is the final step in meeting the patentability requirements and demands that the invention shall be susceptible of industrial application. According to article 57 EPC the requirement is met if the invention can be used in any kind of industry. Where no practical use is suggested in the patent application, the industrial applicability requirement cannot be met; it should not be up to the examiner to find a way to exploit the invention. Although the sounding of article 57 EPC seems to be perfectly clear, the requirement has come to cause many problems for biotech companies trying to patent their inventions.

4.2.3.1 Industrial application and DNA Sequences

When biotech companies and universities began patenting the human genome, many claims involved gene sequences without known functions. Such were the case with the patenting of ESTs and it was feared that patents would be granted allowing protection over products that had no use at the time and at the same time exclude others from using the patented product. The patent offices responded accordingly and today the industrial application requirement is perhaps the most important criterion in the biotechnology field as it can be used to limit the scope of protection given to the patent, perhaps more so than any of the other patentability requirements.[89]

The importance of the industrial application requirement lies in that it excludes patents on DNA sequences that cannot be used in industrial activity. In this aspect it is not sufficient to show how the sequence is manufactured, it is required by the inventor to disclose a specific, substantial and credible use in the application in order to obtain the patent. Speculative uses will not be allowed by the EPO.[90] This means that merely the fact that the substance can be produced is not a guarantee that the requirement is fulfilled, there has to be some profitable use for which the substance can be employed. The underlying reason of the industrial application requirement is that the patent system should not reserve an unexplored field of research for an applicant, but reward inventors that can put the patent into use.[91]

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[87] See Lentz, E. Are Real Business People So Easily Thwarted? p. 443. See also T111/00 Monokine/FARBER Decided February 14, 2002.
[88] SOU 2006:70 p. 35.
[89] Conley, J. Rethinking the product of nature doctrine. p 11.
[90] Decision of the Opposition Division, Official Journal of the EPO, 6/2002, (2002), pp. 293–308.
[91] T 870/04 BDP1 Phosphatase/MAX-PLANCK, see page 2 of the case.

With the emergence of the Biotech Directive, it is now a requirement according to article 5(3) that in order for a biotechnological invention to be patentable, the industrial application must be disclosed in the patent application. There has been a significant debate whether the Biotech Directive demands that, in order to fulfil the industrial application requirement, the inventor also has to include the industrial application in the claim of the patent application and therefore limit the scope to the stated purpose. The ambiguities have led to different implementations of the Directive around Europe, where France and Germany stands out, as they have decided to only allow patents on purpose-bound basis.[92]

4.2.3.2 Difficulties in meeting the requirement

The requirement of industrial application began to increase in importance throughout the 1990s, not least because of the Biotech Directive, and is now one of the most important criteria in biotechnical patent applications.[93] Not only does it demand that the inventor discloses a specific use for the invention, but it can also be an important factor in limiting the claim and thereby limiting the scope of protection. However, it is only in recent time that the requirement has become a major issue in biotech patents. The attempt to patent ESTs without known functions forced the patent offices to alter the regulations regarding the requirement and in 2001, the United States promulgated new Utility Guidelines to clarify the regulations on gene fragments.[94] The guidelines have come to have a massive effect on the way the industrial application requirement is interpreted all over the world, the obvious example is the change in EPO case law that demands the application to hold a specific, substantial and credible use.[95] The stricter utility guidelines in the United States have recently been tested in court in "In re Fisher" decided by the United States Court of Appeal in September 2005. The Court decided to uphold the USPTO's rejection of a patent application based on ESTs because the application lacked utility. As a consequence, an extremely large number of EST claims have been withdrawn, as many believe that their application will not be able to meet the patentability requirement for utility.[96] The consequences at the EPO are probably yet to be seen, but it is certainly a move in the right direction if we can see a similar effect in Europe as the patenting of ESTs often represent the most problematic applications in the field of gene patents.[97]

[92] A further analysis on the purposes of the Biotech Directive and the German and French way of handling the Directive will follow under the section purpose-bound patents.
[93] Bostyn, S. Patenting DNA sequences and Scope of Protection p. 52.
[94] USPTO Utility Examination Guidelines Fed. Reg. 66: 1092, 5 Jan 2001, the term utility is in principle the United States equivalent of industrial application.
[95] See the ICOS-case
[96] Utility is the United States counterpart to industrial application.
[97] Hopkins, M. The Patenting of Human DNA: Global Trends in public and Private Sector Activity (The PATGEN Project) p. 27.

4.3 Disclosure

The disclosure requirement is one of the foundations of the patent system. Not only does it allow the information about the invention to be publicly available, it is also crucial for the patent offices to determine if the invention fulfils the requirements of novelty, inventive step and industrial application. Therefore, it is of significance that the disclosed information enables the skilled person to reproduce the invention in order for others to be able to conduct research and invent around the patent.[98]

The requirement is regulated in article 83 EPC and requires the invention to be disclosed in a manner sufficiently clear and complete to be carried out by a person skilled in the art. As mentioned, the person skilled in the art should basically possess the same knowledge whether it is a question of disclosure or assessing the inventive step (see for example T60/89). The disclosure requirement is crucial as it gives the EPO the chance to balance the protection between fair protection of the invention and the interest of the public to learn about the new invention. This balance act is however not only governed by the way the inventor discloses the invention, it is also governed by the interpretation of the novelty and inventive step requirements, where the latter in particular should be considered side-by-side the disclosure requirement. The patent offices need to examine how innovative the invention is, i.e. what degree of inventive step there is, and determine whether the breadth of the claim is suitable. If the invention holds a high degree of inventiveness, the patent office might be more inclined to allow a broad patent.[99] The Technical Board has held that "*a proper balance must be found between, on the one hand, the actual technical contribution to the state of the art by said invention, and, on the other hand, the terms in which it is claimed, so that, if patent protection is granted, its scope is fair and adequate*", meaning that the inventor should not receive a broader scope of protection than the technical contribution the invention provides to the state of the art.[100].

4.4 The effect of the patentability requirements on the scope of protection

There seems to be consensus amongst experts that the threshold to meet the patentability requirements at the EPO has become considerably higher in recent time. During the period 1996-2000, only 8 percent of the patent applications relating to human DNA were granted, whereas in the years 1980-1989, 45 percent were granted. There also seems to be a common perception that the EPO is being severely influenced by the stricter utility

[98] Radder, H. Exploiting abstract possibilities: A critique of the concept and practice of product patenting, p. 3.
[99] Jaenichen, H. From Clones to Claims p. 165.
[100] T694/92, see also Jaenichen, H. From Clones to Claims p. 165.

guidelines issued in the United States in 2001, meaning that we might see those numbers reduced even further.[101] On the plus side, the more stringent approach adopted by the patent offices seems to have the effect that once the patent is granted nearly all of those patents are maintained.[102] It has been suggested that by granting fewer patents but with an overall higher quality, it might have a positive effect on development, as researchers do not have to worry about the validity of their patents.[103]

The stricter interpretations of the patentability requirements means that fewer patents will be granted but it also means that the patentability requirements supports the patent system by excluding inventions that would only be protected by an extremely narrow scope. By raising the threshold for reaching the novelty and inventive step requirements, inventions with a low contribution to the state of the art will be excluded from patentability. This means that we will avoid seeing patents on "trivial" inventions being granted by the patent offices, and consequently many patents with an unsatisfactory scope will be avoided.[104] The novelty and inventive step requirements are also thought to limit the amount of absolute product patents allowed. Contrary to earlier case law, many believes that a DNA sequences already available through the HUGO project might not qualify as novel or inventive if the DNA sequence is retrieved without inventive effort. It will also be interesting to see to what degree known genes in other species will exclude the possibilities to obtain an absolute product patent with regards to the novelty or inventive step not being met.

The benefit of the industrial application requirement lies in that it excludes non-useful inventions from obtaining a patent and although it is unclear if the Biotech Directive advocates that the patent is limited to the specific purpose named in the application, at least it excludes patents that cannot be used in any kind of industry. As we have seen, the requirement has grown in importance during the years and it will be highly interesting to see if the development in the United States following the decision "In re Fisher", with the withdrawal of a large number of patent applications relating to ESTs, will have the same effect in Europe.

It should be clear that depending on the interpretation of the disclosure requirement set out in article 83 EPC that it could be an extremely valuable resource to control the scope and tackle overly broad claims. With a correct appliance of the disclosure requirement, it is possible to exclude broad patent claims that do not correspond with the contribution to the state of the art.[105]

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[101] Hopkins, M. The Patenting of human DNA: Global trends in Public and Private sector Activity (the PATGEN Project) p. 16, 37.
[102] See for example Hopkins, M DNA patenting: The end of an era? p. 186, 96 percent of all EPO patents are in force in the United Kingdom, France and Germany.
[103] WHO, Genetics, Genomics and the patenting of DNA p. 40.
[104] Bostyn, S. Patenting DNA sequences and Scope of Protection p. 57.
[105] Domeij, Pharmaceutical patents, p. 63.

5 Absolute Product Patent or Purpose-Bound Protection?

In the section above explaining the patent system in general, three different types of patents were presented, product patents, process patents and use patents. The different types of patents all have their benefits and weaknesses. While product patents seems to be preferable for the inventor as it will potentially allow a stronger protection, competitors will argue that a product patent will have anti-competitive effects as they cannot enter the field without infringing the patent holders right. The aim for this section is to focus on the absolute product patent and the limiting purpose-bound patent in order to provide a deeper analysis of the effect the different types of patents have when granted on human genes. Thus, benefits and disadvantages of both types of protection will be presented along with their impact on innovation and research.

5.1 Absolute product patent

In the aforementioned Diamond v. Chakrabarty, the USPTO actually had to deal with two different claims, not only did Chakrabarty claim the bacterium per se, he also tried to patent a method to use the bacterium to degrade oil. The fact is of interest here because the claim for using the bacterium was granted in just two years, whereas the claim on the bacterium per se would take almost nine years to be granted.[106] Admittedly, the case went to the highest instance and the case would prove to become one of the most important in the biotechnological field. Nevertheless, the Chakrabarty case gives an indication that per se patents can be a considerably harder for the patent offices to deal with and may demand a great deal of reflection and consideration.

5.1.1 History of per se claims

Providing absolute product patent protection is a relatively new aspect of patent law. Stumbling across an article in "The journal of industrial and engineering chemistry" from 1918, K.P McElroy writes: "*There is not, never was, and likely never will be a "product patent:" a patent on a product as a product*."[107] With the benefit of hindsight, the suggestion is of course amusing, however, at the time, the conclusion made perfect sense.

The possibility to patent chemical compounds per se has its origin in the United States shortly after the Second World War ended, when penicillin became the first substance claimed this way.[108] Meanwhile, in the United

[106] http://www.gene-watch.org/programs/patents/patenting101.html (2007-03-29)
[107] McElroy, Product Patents, p. 257.
[108] SOU 2006:70, p. 105.

Kingdom, an amendment to their patent law in 1919 made it perfectly clear that the patent did not cover the substance itself, and it would take until 1949, when the United Kingdom replaced their patent statute, before per se claims were to be allowed. At the time, a governmental report said that the provision had little practical value, as creative patentees managed to get around the prohibition by claiming all possible methods to produce the chemical compound, which resulted in that protection was actually given to the compound itself.[109] Although no longer prohibited, the United Kingdom and the United States were the only two countries that expressly admitted patents per se claims in their patent acts. It would take until the end of the 1960s before per se claims started to be accepted throughout Europe, beginning with Germany's initiative to allow product patents in 1968. Today, per se claims are required by the TRIPS agreement and accepted by the EPO.[110]

5.1.2 What does an absolute product patent mean?

An absolute product patent is characterised by the fact that it is not necessary to specify in the claims the specific purpose for which the invention is intended to be used. Instead, the patent will cover all uses of the patented invention, disclosed or not disclosed. Although the possibility to obtain an absolute product patent is not explicitly covered in the EPC, EPO case law confirms that when a claim relates to the substance per se it provides protection for all uses of the substance whether known or unknown.[111] The absolute product patent refers to the compound, or in our case, the DNA sequence per se and protects any using, making and vending of the structure, meaning that if anyone wants to utilise the product, they cannot do so without infringing the patent, unless the patent holder gives actual consent, often by providing a license.[112] Although it should be emphasised that an absolute product patent is not per se a strong protection, by protecting all uses, even if they are not included in the patent application, chances are that the protection will be stronger than desirable. However, this is a statement that needs some amending, as the scope of protection is not only determined by the type of protection, but also by the interpretation of the patentability requirement and the disclosure requirement. In this aspect, the disclosure requirement is particularly relevant. By a correct interpretation of the disclosure requirement, new functions on the patented gene do not necessarily fall under the scope of protection and may be patentable. Although not covered by the scope of protection it cannot be

[109] White, A. Gene and Compound Per Se Claims: An Appropriate Reward?
[110] See G2/88 Friction reducing addictive/MOBIL OIL. See also article 27 TRIPS: *"…patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability"*.
[111] G2/88.
[112] White, A. Gene and Compound Per Se Claims: An Appropriate Reward?

avoided that these patents will become dependent on the product patent as the new function inevitable will have to use the patented DNA sequence.[113]

In able to obtain an absolute product patent the DNA sequence must not be known, meaning that if the DNA sequence has been identified before, it is not possible to obtain an absolute product patent. Instead, the inventor will have to rely on the possibility to obtain a use patent that only protects the specific use the inventor discloses in the application. It should be pointed out that the DNA sequence is not considered to have been identified before only because of the fact that the sequence is included in a previously known, longer sequence. In order to exclude the gene from an absolute product patent it is necessary that the specific DNA sequence has been identified.[114] As mentioned above, it is also believed that the mapping of the human genome in the HUGO project will lead to that fewer product patents will be granted as much of the novelty value has been destroyed. Instead, future inventors will most likely focus on the possibility to obtain use patents or process patents.[115]

5.1.3 Dependent Patents

Although an absolute product patent gives the patent holder the right to all uses over the patented DNA sequence, the possibility to patent future uses is not entirely exhausted. If a competitor is able to find new uses for the patented sequence that could not have been foreseen by the inventor, the new use can enjoy patent protection as well. This patent will however be a use patent and not a product patent and will be dependent upon the product patent. Consequently, the competitors use patent cannot be used in commercial activity without an agreement with the original patent holder, i.e. the product patent holder.[116]

In addition to being able to patent new uses, there is also a possibility to patent a first medical indication on the gene even if an absolute product patent covers the invention. The possibility to protect a first medical indication is in accordance with article 54(5) EPC and means that if someone other than the patent holder of the absolute product patent discover that the gene sequence can be used in the treatment for a certain disease, it might be possible to obtain a patent for that treatment. Should the original patent holder already possess a patent on the first medical use, which is often proved to be the case, there is a possibility to obtain a patent on the second medical indication.[117] Just like a patent covering further uses, this

[113] Bostyn, S. Narrow trousers and narrow patents, a Health risk?
[114] Prop. 2003/04:55 p. 90-91.
[115] See SOU 2006/70 p. 207 and the Australian Law Reform Report chapter 6 section 150.
[116] Nuffield, p. 31-32.
[117] According to EPO case law G5/83 Second Medical Indication/EISAI. The concept of first and second medical indications shall be further explained in the next section covering the purpose-bound patent as many authors have likened these sorts of patent to the purpose-bound patents called out for to use when claiming genes as patents. See for example White, A. Gene and Compound Per Se Claims: An Appropriate Reward?

patent will also rely on the original patent, meaning that a patent on the first or second medical indication will also become a dependent patent.

5.2 Purpose-bound protection

The general rule in DNA patenting, as well as in patenting chemical compounds, is that a product patent confers rights over all the uses of the patented product. However, in recent time, this approach has been questioned by many leading experts and organisations, claiming that the absolute product patent is not a suitable type of protection for human DNA sequences. Instead, they believe that there are better alternatives.

Perhaps the most suitable and most advocated alternative to the absolute product patent protection is the purpose-bound protection, which in contrast to the absolute product patent would extend no further than the use disclosed in the application. Thereby, the scope of protection would be limited to a specific use and exclude uses the inventor did not include in the patent application. This means that if an inventor manages to find that a gene codes for the protein A, a purpose-bound patent would extend no further than the use for the protein A. If a competitor after that finds out that the gene also codes for the protein B, the competitor can file an independent claim for that use.[118] The purpose-bound protection is a product patent and should not be confused with the use patent, the use patent does not provide any protection over the product as such but only for the use of the product, whereas the purpose-bound product protection protects the actual product but the protection is limited to the disclosed purpose.[119]

This form of claim that does not extend beyond the stated purpose has a high resemblance with the so-called “Swiss”-claims that are being used for protection of a second medical use of a known substance and allows multiple purpose-bound patents to be granted for the same chemical compound. It means that if a company for example finds out that a medicine used to treat peptic ulcer also works as an effective method of abortion, it is possible to patent the second medical indication, even though a patent already covers the treatment for peptic ulcer.[120] As we have seen, the possibility to patent a first and second medical use is today possible even when the invention is covered by a product patent. Instead, what is argued here is a system based on the medical indication patents but without the possibility to obtain an absolute product patent. It means that the scope of

[118] The example is borrowed by Dutfield, G. Biotechnology and IPRs in Europe.
[119] Bostyn, S. Protection of biotechnological inventions in France and Germany after directive 98/44/EC, p. 2.
[120] The example is base on the medicine cytotec, used by Swedish abortion clinics although it is originally a medicine for treating peptic ulcer. Regarding cytotec see www.fass.se, see also http://www.svt.se/svt/jsp/Crosslink.jsp?d=27055&a=733595 (2007-05-04). The example is meant to be hypothetical to exemplify the meaning of patents on second medical indication, the patent on cytotec expired in the United States in July 29 2000, and since the product is no longer protected there is no need for a patent on the second medical indication.

protection will be limited to the specific new indication, with further new indications not falling within the scope of protection. By that, it allows several purpose-bound patents being granted on the same DNA sequence, without them being dependent patents.[121]

Protection for first and second medical indications is not required by the TRIPS agreement but many countries have allowed this sort of claims in their national patent law, so also the EPO. According to the EPO Guidelines for Examination it is possible to obtain a patent on a known substance or composition when the substance was not previously disclosed for use in surgery, therapy or diagnostic methods practised on the human body. This is an exception from the general principle of absolute novelty and allows the inventor to patent a first medical indication, provided the substance meets all other patentability requirements.[122] The approach has also been confirmed by the Enlarged Board of Appeal that held that using a known substance in a new way might be novel, but using a known substance in a known way to produce a new purpose does not meet the novelty requirement.[123] The possibility to patent a second medical indication has been a debated issue throughout Europe, especially since the EPC does not contain any provisions expressly allowing patents on further medical indications.[124] However, case law from the EPO confirms that it is possible to patent further medical indications under the EPC.[125] The case law has however undergone hefty criticism, from amongst others the United Kingdom. In response to the criticism, the EPO has decided to add an amendment to article 54 in the new EPC 2000 that expressly allows protection for a second medical indication.[126]

5.3 The ambiguous Biotech Directive

With the issuance of the Biotech Directive in 1998 the debate on a purpose-bound product protection for DNA sequences started to take a new turn as proponents argued that the legislator had a purpose-bound protection in mind when they drafted article 5(3) Biotech Directive. The article states: "*the industrial application of a DNA sequence or partial sequence must be disclosed in the patent application*". The wording of article 5(3) together with recitals 23 and 25 has been seen by many as request to limit the protection to the specific purpose included in the application.

Due to the ambiguities in the Biotech Directive, the different member states have chosen different paths in the implementation to national law, in what they think is in accordance with the Directive. The consequences of this began to show in late 2004 when both France and Germany implemented

[121] Domeij, B. Pharmaceutical patents in Europe, p. 187.
[122] EPO Guidelines for Examination Part C, Chapter IV, section 4.2.
[123] Mobil/Friction reducing additive G2/88 [1990] EPOR 73. See also Gibson, J. The Discovery of Invention Gene Patents and the Question of Patentability, p. 5.
[124] Domeij, B. Pharmaceutical patents in Europe, p. 182.
[125] G5/83 Second Medical Indication/EISAI
[126] SOU 2006:70 p. 120.

the Directive into their national laws. According to the new legislation in Germany, it is still possible to obtain a product patent; however, the use of the human gene sequence must be disclosed in the patent claim, meaning that patent protection is only available for the specific function of the human gene.[127] This means that it is no longer possible to obtain an absolute product patent on human genes in Germany. It is obvious that Germany has decided to allow special treatment for human genes, as it is still possible to obtain an absolute product patent on animal and plant genes.[128] In a way, the French legislator seems to have done the same as the German, although it is difficult to understand the true meaning of the implemented Directive in French national law. Article L 611-18 in the French Code la Propriété Intellectuelle (CPI) seems however to suggest that not only is the absolute product patent abandoned in relation to human DNA sequences, they seem to have abandoned the possibility to obtain an absolute product patent for DNA related inventions altogether.[129]

At the other end of the scale, there is the United Kingdom, who has closely followed the wording of the Biotech Directive and subsequently decided to allow absolute product patents. The consequences of the different ways of handling the issue are yet to be seen but it will be highly interesting to see how the different approaches will affect innovation and prices on healthcare.[130]

Although the French and German approach of interpreting the Biotech Directive is probably not what the legislator had in mind when the Directive was issued in 1998, their interpretation seem to have been welcomed by the European parliament. In a resolution in patents for biotechnological inventions issued in October 2005, the European Parliament calls upon the EPO to grant patents on human DNA sequences only on purpose-bound basis.[131]

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[127] See paragraph 4 of section 1a in the German patent act (patentgesetz): *Ist Gegenstand der Erfindung eine Sequenz oder Teilsequenz eines Gens, deren Aufbau mit dem Aufbau einer natürlichen Sequenz oder Teilsequenz eines menschlichen Gens übereinstimmt, so ist deren Verwendung, für die die gewerbliche Anwendbarkeit nach Absatz 3 konkret beschrieben ist, in den Patentanspruch aufzunehmen*. Available at: http://www.patentgesetz.de/ (2007-06-17).

[128] Zimmer, F-J. Act Implementing the Directive on the Legal Protection of Biotechnological Inventions in Germany, p. 561, 564.

[129] Bostyn, S. Protection of Biotechnological inventions in France and Germany after Directive 98/44/EC, p. 2-4. The French legislation reads: *Le corps humain, aux différents stades de sa constitution et de son développement, ainsi que la simple découverte d'un de ses éléments, y compris la séquence totale ou partielle d'un gène, ne peuvent constituer des inventions brevetables. Seule une invention constituant l'application technique d'une fonction d'un élément du corps humain peut être protégée par brevet. Cette protection ne couvre l'élément du corps humain que dans la mesure nécessaire à la réalisation et à l'exploitation de cette application particulière. Celle-ci doit être concrètement et précisément exposée dans la demande de brevet.*

[130] http://www.wptn.com/Mailing/Feb_2007_4/details/patents/divergent.html (2007-03-29)

[131] European Parliament resolution for patents on biotechnological inventions. The absolute product patent is also available in the United States and Japan, see Köster, U. Absolute or limited Product protection for Biotech Inventions, p. 1.

5.4 The debate

The main reason for allowing an absolute product patent is that by limiting the protection inventors will not be rewarded adequately and will thereby not find the incentives to commit themselves to an unexplored field. The view is however challenged by opponents saying that the arguments laid down by the proponents are exaggerated and that the absolute product patent does not provide incentives to the degree proponents wants us to believe. Instead, by allowing an absolute protection, research and development might be hampered since the degree of protection will be too broad. It is further argued that by not allowing absolute product patents we will see an end to the dependency problems and make it easier to define the outer boundaries of what is protected.

It is suitable to anticipate the debate already at this point and call attention to that there are some inconsistencies in the arguments from proponents of the absolute product patents. On the one hand, they argue that a strong protection is needed to protect the assets of the biotech companies. On the other hand, they argue that, due to the strict assessment of the patentability requirements, the scope of protection will not be much broader than the purpose-bound protection, implying that a strong protection might not be necessary for biotech companies to survive.[132]

In the following pages, the debate between proponents of the absolute product patent and proponents of the purpose-bound patent will be presented. Instead of presenting all the benefits of the absolute product patent under one section and all benefits of a purpose-bound protection under another, I have chosen to present the debate under the main arguments both sides have. This means that under each of the following five sections, arguments and counterarguments from both sides will be presented.

5.4.1 Increased incentives to conduct further research and keep the invention out of secrecy

There are obvious economic advantages with a patent asserting rights of all uses of the DNA sequence, certainly so in the eyes of the patent holder. By obtaining a patent for all uses, all other patents on the sequence will be dependent on the product patent, giving the inventor the chance to recoup the expenses not only on his own uses, but he will also be able to profit from the dependent patents in form of licensing fees.

Proponents to the absolute product patent express their worries by saying that a change in the current legislation would have detrimental consequences on innovation and investment. Developing biopharmaceuticals is a long process that demands extremely large resources and it is approximated that

[132] See for example Bostyn Patenting DNA sequences and Scope of protection, p. 66.

only one in ten pharmaceuticals eventually reach the market. In most cases, biotech and pharmaceutical companies rely heavily on their patent rights, as they are often the most valuable asset of the company. Therefore, a strong protection is essential as an incentive for biotech companies to continue their research. It should be recalled that the biotech and pharmaceutical sector are not alone in their research of the human genome or developing new pharmaceuticals as the sector is balanced by publicly funded research. However, the economical resources at disposal in the public sector are extremely limited in comparison with the resources available in the private sector.[133] Thus, the pharmaceutical sector is an extremely valuable resource in terms of research and development made in the field.

Although the patent system aims to compensate inventors for their research and development, put in a wider perspective the purpose of the patent system is to benefit the entire society. The idea is that by providing an exclusive right to the invention, the inventor will be more inclined to apply for a patent. At the same time, the information about the patented product will be exposed to the public, enabling others to try to improve the invention without having to first re-invent the invention. By knowing that an absolute product patent is available, inventors might be more willing to apply for the patent and put the information in the public domain, as they know that they will receive sufficient protection.[134]

It is however disputed whether the absolute product patent fulfils its purpose of keeping the information out of secrecy. Opponents of the absolute product patent argue that, as there is a strong possibility that the patentee will obtain a strong protection it encourages inventors to apply for patents for DNA sequences in early stages, before all utilities are known. Consequently, this leads to the total opposite of what the patent system strives to achieve. If a patent is granted in early stages the utilities not known at the time will obviously not be unveiled to the public as they are of course unknown. Even worse, by granting patents on early stage inventions it might become harder for others to gain access to the information and thereby make the field exclusive for the patent holder. To a high degree, the problem with patents on DNA sequences without known utilities are today tackled by the patent offices stricter approach to the patentability requirements, nevertheless, we may still see a problem where the inventor manages to find a use on an early stage invention.[135]

Opponents further argue that the effect an absolute product patent has on innovation is far exaggerated by its proponents. Rather, the absolute product patent might be detrimental for the economic landscape and increase

[133] In 1998, the pharmaceutical industry in the United Kingdom spent £2,4bn, whereas the British government spent £800m. In the year 2000 in the United States, the private sector spent an estimated $2,2bn on research and development in the genomic field, whereas the government spent $360m. See In defence of gene patents p. 136 and Bjornstad, D. An introduction to issues underlying patent policy for the emerging genetic information and medical treatment industry, p. 10.
[134] See Bostyn, S. Patenting DNA sequences and Scope of Protection p. 24-25.
[135] Nuffield, p. 65.

transactions costs for new inventions.[136] Every negotiation is associated with a transaction cost and if the cost becomes too high it will deter companies from entering the contract. In this case, transaction costs will be increased where the competitors are required to obtain a license before using the gene. It will increase their costs for making the invention and in worst case mean that it is not profitable to obtain the license. In a broader view, this might hamper research and deter others from entering the field. It is argued that, unless you are first on the patent scene, when all you can achieve is a dependent patent that require a license, there will be less economical incentives to place a considerable amount of money on research and development when you know that you will have to share your profit with the product patent holder.[137]

5.4.2 Why treat DNA sequences different than other inventions?

There are many different reasons to treat the human genome differently from other chemical compounds, after all, it is our common heritage that is being patented. The fact that we have other feelings towards patents on our own DNA raises this debate to another level, not least on the ethical plane. For the purposes of this thesis, it is sufficient to know that there is a significant ethical debate going on, unfortunately there is not enough space to present these arguments here.[138]

The objection that patents on human DNA sequences should be treated differently from other chemical compounds is connected with the special features of the human gene. It has been showed that a single gene may be involved in the production of a ten- or twentyfold number of functional proteins. The complexity of the DNA sequence makes opponents to the absolute product patent argue that there is a strong possibility that the inventor will be over-rewarded if he is allowed protection for uses never thought of.[139] Although the over-rewarding objection could be raised with any patent allowing protection over the product per se, due to the multi-functionality of the gene it is said to be an increased risk for harmful consequences, as the inventor will benefit from the invention on the cost of the society.[140] This would go against one of the most common justification

[136] Transaction cost is a term in economic theory relating to the cost of concluding a deal. Every type of purchase has a transaction cost, it might be a cost for contact or it might be a cost for negotiation. In economic theory, it is often desirable to imagine a world without transaction costs in order to determine how rights and obligations should be allocated. See Dahlman, C. Rättsekonomi, p. 103. See also Bostyn, S. Patenting DNA Sequences and the Scope of protection, p. 59.
[137] SOU 2006:70 p. 31.
[138] For an introduction on the ethical debate, see for example Patenting Human Genes and Stem cells, A Report from the Danish council of ethics 2004, SOU 2006:70 p. 56-67 and Nuffield Council of Bioethics, the ethics of patenting DNA.
[139] Who owns the human genome? What can ownership mean with respect to genes? Hubert Markl p. 516.
[140] SOU 2006:70 p. 131.

of the patent system, the reward-theory, saying that an inventor should not be able to reap more than he sows.[141]

Closely related to the multi-functionality objection is the argument that the gene is extremely hard to invent or design around, making patents on DNA sequences stronger than patents in other fields. The possibility to invent around the invention is one of the cornerstones of the patent system as it inspires competitors to try to find better and less expensive alternatives to the patented product. However, this is where the gene differs from traditional chemical compounds, because where traditional chemical compounds might be possible to invent around,[142] this might not be the case with gene-related diseases. As there are often no alternatives in terms of coding for a specific protein than to use the gene, it leaves the competitors dependent on the patented sequence and the good will of the patent holder to allow a license.[143]

Proponents of an absolute product patent questions why DNA sequences should be treated differently than other inventions. In terms of patent law genes classifies as chemical compounds and these are not excluded from obtaining a patent on the compound per se.[144] In relation to this one must also highlight the TRIPS agreement, where article 27(1) requires that protection is available for all sorts of inventions without discrimination. Although the interpretation of the article is not settled, it is not unlikely that the article might prohibit the introduction of a purpose-bound protection. Having said that, we have already seen several countries introduce a purpose-bound protection, however, that does not mean that it is justifiable by article 27(1), and a unison interpretation of the article would be preferable.[145]

Moreover, the multi-functionality objection is met with scepticism from opponents of the absolute product patent. Although it is true that many traditional chemical compounds lacks multifunctional features, this is not the case with all chemical compounds. For example, both Aspirin and Viagra are known to have various functions.[146] The multifunctional features in these compounds have not led to the controversy seen in the field of DNA sequences, implying that there is something else behind the objection than the argument about multi-functionality.[147] Furthermore, just like chemical compounds not all genes are multifunctional. In cases where the gene lacks

[141] Domeij, B. Pharmaceutical Patents in Europe p. 73.
[142] There are for example many different chemical compounds available to treat headache.
[143] OECD p. 11, 22.
[144] White, A. Gene and Compound protection per se claims: An appropriate award?
[145] OECD p. 43-44.
[146] Aspirin was originally a pharmaceutical for treating headache, later it was discovered that the product also had beneficial effects in certain types of heart diseases. Knowles, J. 2nd Pharmaceutical use – the Swiss type claim, available at http://pharmalicensing.com/articles/disp/977438120_3a4285a8a07d8 (2007-05-26). Regarding the multi-functionality of Viagra and its active substance sildenafil see www.fass.se (2007-05-26).
[147] Bostyn, S. Patenting DNA Sequences and the Scope of protection, p. 60.

multifunctional elements the differences between an absolute product patent and a purpose-bound protection will not be so obvious.[148]

5.4.3 An absolute product protection would provide an excessive degree of protection

As mentioned above, the absolute product protection does not per se equal a broad scope. However, when protecting all uses on the patented product chances are that the provided protection will be unsatisfactory in its scope. As we have seen under chapter three, allowing a broad scope means that it will be harder for competitors to enter the market without facing litigation for patent infringement. Moreover, it also means that the company possessing the patent might be more inclined to use its right strict, in a similar way to what Myriad did with the BRCA1 patent, meaning that we would see an increase in healthcare costs. If the patentee chooses to exercise his rights strict it will most probably also mean that a license will be harder to come by or at least become more expensive, as the patent holder will want as much control as possible and will demand a higher price for the license.

Advocators to the absolute product patent admit that there is a possibility that the scope given to the invention will be far broader than desirable. However, they believe that the mitigating factors the patent system provides are sufficient to keep most of the potential harmful effects away. By being able to receive patents for further uses or further medical indications the scope is severely narrowed, and even if there will be a dependency situation that does not necessarily mean that the scope is overly broad. As for the fact that it might be hard to obtain the license, proponents points to the fact that in worst case scenario a compulsory license might be obtainable. However, some would argue, the compulsory license would not be obtainable without much trouble and even if a compulsory license were provided, it would probably require a cross-license to be provided to the first patentee.[149]

Furthermore, the potential harmful effects of an absolute product patent are balanced by the patentability requirements and the disclosure requirement. As we have seen in the previous chapter, the possibility to exclude inventions that lack novelty value or inventive step will exclude many patents with unsatisfactory scopes. The completion of the HUGO-project probably means that fewer patents on the product per se will be granted due to the sequences no longer being novel. It is also believed that future patent claims will be narrower since the claims will relate to the DNA sequence as part of the invention rather than being the main focus.[150] This is not to say that product per se claims should be excluded from patentability, rather, if an inventor manages to meet the patentability requirements and isolate a

[148] SOU 2006:70 p. 131.
[149] White, A. Gene and Compound protection per se claims: An appropriate award? See also Bostyn, S. Patenting DNA sequences and the scope of protection p. 60.
[150] Hopkins, M. The Patenting if human DNA: global trends in public and private sector activity (The PATGEN Project), p.37.

new gene it should be possible to obtain a protection on the gene per se. With the higher threshold demanded for the industrial application requirement it would no longer be possible to obtain patents, not least a product patent, on a DNA sequence that cannot be used in any kind of industry. Therefore, many of those patents obtained in the early days of patenting gene fragments would not be able to meet the industrial application should an inventor try to receive a patent on, for example, an EST without known function. When discussing mitigating factors within the patent system one cannot forget the disclosure requirement that might be the most useful requirement to regulate the scope. Here, the patent offices need to find the proper balance between the actual technical contribution and the manner of claiming so that the scope of protection is fair and adequate.[151]

It should also be noted that even if a strong protection is allowed, research on the gene is not reserved for the patentee. Due to the research exemption widely available across Europe, third parties are allowed to use the patented gene in scientific research without infringing the patent. It is only the commercialisation of the finished product that requires a license from the patentee. At that stage, an agreement to cross-license the product is often available.[152]

5.4.4 Defining the scope

Proponents of limiting the scope argue that by only allowing patents on a specific purpose it will be easier to get an overview of the patented area, as it is hard to define the outer boundaries of the invention if it is covered by an absolute product patent. Limiting the scope will make it easier for companies to know whether they could enter a field without committing patent infringement as the purpose-bound protection would provide a clearer definition of what is being patented.[153]

However, this might not necessarily be true; opponents of a function limitation argue that although a purpose-bound protection will only allow protection for a specific purpose it will not make it easier to overview the patented area. While it is true that a broad patent covering the DNA sequence tends to lead to difficulties in determining the exact scope, one cannot forget the doctrine of equivalence that exists in most European countries.[154] The doctrine of equivalence allows protection not only for the literal wording of the claims but also against inventions with improved functions that are equivalent with the original invention.[155] In the view of the doctrine of equivalence, by only allowing multiple purpose-bound patents chances are that the uncertainty of the scope will not be solved, as the scope of protection will nonetheless extend beyond the literal claim in

[151] Jaenichen, H-R. From Clones to Claims p. 165.
[152] Domeij, B in an article in Dagens Nyheter from 2002. See also Bostyn, S. Patenting DNA sequences and Scope of Protection p. 61.
[153] Bostyn, S. Narrow trousers and narrow patents, a Health risk?
[154] See above under section 3.3”Different types of patents”.
[155] Levin, M. Immaterialrätt p. 285.

the patent application. Thus, while a purpose-bound protection at first sight seem to provide a clear definition of the scope, it will still be difficult to know whether a new invention falls under the equivalency protection of the already patented invention.[156] Moreover, what if an inventor invents a DNA sequence that can be used in the treatment of cancer, will the patent be limited to that certain type of cancer, or will the purpose be seen as cancer in general? It would be extremely difficult to define the scope of protection and it would require a lot from patent examiners and patent lawyers to formulate and interpret these claims so that the scope will be fair and adequate. Therefore, allowing patents only on the disclosed purpose would lead to the same sort of problems that an absolute product protection, i.e. difficulties in defining the exact scope. [157]

5.4.5 Lesser Dependency problems?

As we have seen, although the DNA sequence is covered by an absolute product patent, it is still possible to obtain patents on further uses and medical indications. However, these patents will be dependent on the absolute product patent and cannot be used without consent from the patent holder. The reasoning for making a patent on new uses dependent on the original product patent has been severely questioned by opponents to the absolute product patent. Due to the importance of genes and their multifunctional features it is not unusual that the newfound use is equally as important for the society as the first found use. Therefore, it is argued that it is not rational to only acknowledge a dependent patent when the achievement of finding a new use for the DNA sequences might be just as great as finding and isolating the gene in the first place.[158]

Even advocators of the absolute product patent acknowledge that dependency issues can be a major concern. However, they feel that the proponents of a function limitation exaggerate the debate. The problems we see with dependency in this field are no different from the dependency problems that are already today evident in many different fields, not least the pharmaceutical field, and that has not sparked the controversy it has done in the field of patenting human DNA sequences. It is nothing unusual about having to negotiate a license before a company can use the product; it is manageable in many other fields, so why should it not be manageable in the field of biotechnology? The licensing fee should not be something that deters companies from research, as it usually does not exceed a couple of percent of the market price.[159] Although it should be highlighted that in

[156] Bostyn S. Patenting DNA Sequences and the Scope of Protection, p. 63.
[157] Bostyn raises this issue in Patenting DNA sequences and the scope of protection p. 63 where he uses this example.
[158] SOU 2006:70 p. 121.
[159] Bostyn, S. A Critical Analysis of the (Non)-Patentability of Diagnostic Methods and Consequences For BRCA1 Gene Type Patents in Europe, see also Domeij, B. Patent ger samverkan kring genforskning in DN October 24, 2002. http://www.dn.se/DNet/jsp/polopoly.jsp?a=69057 (2007-05-20).

extreme cases the price for an exclusive licenses can be as high as 20 percent of the net price.[160]

Furthermore, it is suggested that by limiting the scope of protection we will not avoid the dependency problems. Instead, by allowing new patents on every purpose of the gene, we might see an increase of phenomenon like patent thickets and royalty stacking. A patent thicket emerges when so many patents cover a field that it is not profitable for the company to try to acquire all licenses needed in order to conduct research in the field. In economical terms, this is often referred to as the "tragedy of the anti-commons", where, because no company possesses enough patents to make commercial use of the research, no one will benefit from the potential invention. In addition, even if a company manages to acquire sufficient licenses to use product commercially, the prices would then be passed on to the consumer making the products more expensive. Closely connected to patent thickets are royalty stacking where a multiplicity of overlapping patents may force up prices on the market and make the product non-profitable.[161] These issues are evident already today, where specifically the biotechnology sector is subject of a higher risk than many other fields because of their high reliance on patents. Therefore, it would not be desirable to take measures that are likely to increase these problems.[162]

In a report from 2002, the OECD has commented on these issues by saying that it is seldom that a project is abandoned just because of the problem with royalty stacking alone. Representatives from the industry acknowledged patent thickets and royalty stacking as real concerns but felt that they did not pose a threat to the innovation in the biotechnology sector, as they recognised that contractual solutions are often available.[163] It is also believed that remedies within the patent system can tackle the potential negative effects of royalty stacking and patent thickets. There are a few basic remedies to deal with this problem. One option is to create a patent pool where patent holders join forces in order to share their resources to keep the price at a lower level. Another option is to cross-license the patents so that both patent holders can benefit from the research of the other.[164]

[160] OECD p. 61.
[161] Australian Law Reform Commission chapter 18 section 13-14. Available at: http://www.austlii.edu.au/au/other/alrc/publications/reports/99/18.html (2007-05-04). The OECD report on genetic inventions suggests that royalties in some cases can hold up to 20 percent of the net price.
[162] Adhikari, R. Patents, Royalty stacking and Management, p. 25.
[163] OECD p. 60, 62.
[164] WHO, Genetics, genomics and the patenting of DNA p. 46 and Scherer, F. The economics of Human gene patents p. 1363

5.5 The impact of patenting DNA Sequences on research, innovation and healthcare

It is hard to estimate the potential consequences an introduction of a function limited protection on human DNA sequences might have, especially since the purpose-bound patent in Germany and France has only been in effect for about two years. It is still too early to draw conclusions on the impact on innovation and healthcare the purpose-bound protection has had in those countries and it will be extremely interesting to see an empirical study in the near future to compare the different systems. What can be said here is that several reports regarding the impact of patenting DNA sequences in general have been issued and it is fair to say that they agree on that the patent protection is essential for the biotechnological sector to stay alive. In November 2006, a comprehensive study examining DNA patents from 1980 to 2003 was published with the aim to analyse trends in filing, granting and exploitation of patents claiming human DNA sequences. At the same time, the report comments on the impact DNA patents have had on innovation and healthcare.[165] Their result shows that the DNA patents have had little impact on academic research, but they point out that the effect will vary between different countries depending on the availability and interpretation of a research exemption.[166] However, others have expressed that there is no data that supports the view that the access to patented genetic material will be significantly affected by the presence or absence of a research exemption.[167] The report then turn to the impact of patenting DNA on innovation, pointing out that the presence of the patent system is essential for biotechnology firms and pharmaceutical companies to continue to invest in the field as the cost for developing the products can be very high. At the end, the report acknowledges that the patentability of DNA sequences has spurred investment in healthcare globally and that the impact the patentability has had on development of the healthcare today cannot be overestimated. They do however express their concern that broad patents such as the original BRCA1 patent may become a substantial problem for European healthcare as it can result in higher prices and less availability.[168] In relation to this it might be suitable to point out that the majority of patents in the field cannot be said to hamper scientific research as their scope is not that broad and in most cases the patent holder is prepared to license the invention at a reasonable price, with BRCA1 being the clear exception.[169]

[165] The Study was done by the University of Sussex in Great Britain and is available online at: http://www.sussex.ac.uk/spru/documents/patgen_finalreport.pdf (2007-05-06).
[166] Hopkins, M. The Patenting of Human DNA: Global Trends in Public and Private Sector Activity (The PATGEN Project) p. 38.
[167] OECD, Research use of patented Knowledge: A Review, p. 24.
[168] Hopkins, M. The Patenting of Human DNA: Global Trends in Public and Private Sector Activity (The PATGEN Project) p. 38-41.
[169] Bostyn, S. Patenting DNA Sequences and Scope of Protection, p. 105.

6 Final Remarks and Conclusions

Bob Dylan once sang *"…ev'rything I'm a-sayin', You can say it just as good…"*, and while Mr Dylan's lyrics are the subject for over-interpretation by devoted fans all over the world, I am fairly sure that he did not have patent law in mind in 1964 when "One too many mornings" was released. Nevertheless, the quote seems to summarise much of the ongoing debate whether the absolute product patent should be abandoned or not. While proponents of the absolute product patent argue that the absolute protection is necessary to spur innovation, their opponents claim that the introduction of a purpose-bound patent will provide more incentives for companies to innovate. And while the proponents of the absolute product patent argue that we will see lesser dependency problems with a protection that confer rights over all uses, proponents of the purpose-bound patent say we will see lesser dependency problems with the purpose-bound patent. I could go on for quite some time, however, that is not my intent as I hope I have made my point clear. However, if we look closely at the issue, it looks as though the whole question boils down to whether an absolute product patent is a reasonable degree of protection or not.

It has been pointed out that there are some inconsistencies in the reasoning from proponents of the absolute product patent. On the one hand, they claim that a stronger protection is essential to spur innovation, while on the other hand claiming that the factors within the patent system can tackle overbroad claims and that the breadth of an absolute product patent would differ only marginally from the purpose-bound patent. Although there are mitigating factors in the patent system, you could assume that the absolute product patent, conferring rights over all future uses, will be broader than the purpose-bound protection.

While we saw a steady increase in the number of patent application from the year 1992 onwards, not only in Europe but also at the USPTO and the JPO, the trend in the last couple of years seems to be that it is not as profitable as it used to be to claim human DNA sequences as patents. Actually, from 2001, we have seen the filing of patents on the human genome somewhat stagnate and the numbers of patent applications claiming product patents on human genes have become fewer by the year. Coincidentally, in 2001, the first drafts of the human genome were released through the Human Genome Project and the United States issued new stricter utility guidelines, setting a precedent for the EPOs way of handling the same questions. Admittedly, the new utility guidelines seem to have made the greater impact of the two factors, but the effect the HUGO-project has had should not be underestimated. While the stricter utility guidelines have raised the bar for patentability, the success of the HUGO-project will probably mean that fewer patents on the product per se will be granted. In that respect we will

probably see less patents granted as absolute product patents covering the entire gene, while those absolute product patents that is granted will be narrower than those patents obtained in the early ages of the "patenting on life" due to the more stringent approach of the patentability requirements adopted by the patent offices. Hopefully, when the problematic early patents expire many of the issues dealt with here will be avoided. It is indicated by several different experts that future patents will be different from the per se patents as finding a completely unknown gene rarely happens nowadays.[170] Instead, future claims will not relate to the DNA sequence as an invention in itself, rather, the DNA sequence will most probably be seen as a part of the invention, thus we might see an automatic shift in the way DNA patents are filed without the legislator having to intervene.

The concern of many following the early patenting of gene fragments such as ESTs were that those patents threatened to reserve a whole research field for one patent holder. The concerns were not unfounded. These early patents on fragments were often granted without the inventor having to show a credible industrial application, thus the patents could be filed at a stage where no use would be known and the scope of those claims would be very far-reaching. Although it is possible to conduct research for purely scientific purposes due to the research exemption widely available across Europe, those broad patents still makes it considerably harder for others than the patentee to enter the market. It is not easy to find the incentives to invest heavily in a field, knowing that the company would have to share the profits with the original absolute product patent holder. Admittedly, these patents were a problem in the beginning of gene patenting, and to the extent they are still protected by a patent they still are, allowing an absolute product patent on gene fragments whose utility is unknown is not acceptable. However, the patent offices has acted against these types of claims and today it is required to show a specific, substantial and credible use, meaning that these types of claims would not be allowed today. With the exclusion of inventions that lacks industrial application and a higher bar for reaching the requirement, we will not see those types of broad patents in the future, even if an absolute product patent should cover the gene.

As mentioned, it seems as though both sides of the debate relies on the same arguments. While the proponents of an absolute product patent argue that a limited protection will not provide the incentives needed to take up or continue research, opponents argue that just because the protection is so broad it will nonetheless not provide sufficient incentives to invest in research. It is not easy to estimate which side is closer to the truth, especially not seeing as there are hardly any conclusive studies comparing the absolute product protection and the purpose-bound protection. What can be said is that the consequences on medical care and research are perhaps not so far-reaching proponents of the limited protection would like us to believe. Things can often get better, but considering the rapid development the biotechnology field has undergone in the last 30 years, the current

[170] See for example Bostyn in Narrow trousers and narrow patents, a Health risk? The PATGEN Project p. 37 and the Australian Law Reform Report chapter 6 section 150.

legislation can hardly be described as a complete failure. It should be recalled that the number of patent applications in the biotechnological field had an annual increase that was considerably higher than average (10, 5% versus 5%) during the years 1990 to 2000, and this was with the absolute product patent available. Of course, the numbers do not only deal with biotechnology patents covered by an absolute product patent, but to suggest that by allowing absolute product patent the consequences in research and healthcare would be detrimental is to ignore those facts we do have. In the last couple of years, we have seen a slight decline in the amount of patent applications filed at the EPO and by just looking at numbers this could certainly be interpreted as a waning interest in patenting human DNA sequences and a disinterest from the industry to invest. However, one must remember that the stricter assessment of the patentability requirements has much to do with it. In the same way the numbers indicating that the patents granted in the years 1990 to 2000, should not be taken as conclusive proofs that the patent system is successful, the numbers from after 2001 cannot be said to indicate that the interest in the field is diminishing. One must bear in mind that there is more behind the statistics than numbers. Although we have seen a slight decline in the amounts of patent applications, a high number of patents are still being filed at the EPO, indicating that the industry still has a high confidence in the system.

It is of the utmost importance to provide a sufficient degree of protection in order to spur innovation and protect biotech companies' assets. Although it has been highlighted that universities and publicly funded institutions to some extent provides us with new inventions, they cannot compete with the private sector in terms of money invested. Thus, it would be detrimental if the private sector were to abandon this field of research. In this respect, a purpose-bound protection might not be a sufficient protection, especially as it is not unusual that the intangible rights are the only assets a biotech company might have, and most certainly their most valuable. By decreasing their protection, we might see fewer biotech companies entering the market and more companies being forced out of the market.

When proponents of the purpose-bound patent implies that the absolute product patent would impose a higher price in medical care, we often see the BRCA1 case mentioned in the same sentence. It is hard to justify the way Myriad chose to deal with the matter, however, as has been pointed out in the thesis, there are not many patents that can be said to affect the market in the way we have seen these few, very debated patents have. Neither could this problem be said to be exclusive for DNA patents covered by absolute protection, the same could be said about any broad patent, absolute protection or not, and we have not seen the same infected debate in other fields where these problems occur. As it is today, the industry has not highlighted the difficulties in obtaining licenses as a factor that makes them abandon projects, and in the end, license fees often do not exceed a couple of percent of the market price. Ultimately, if a project has a great deal of commercial potential it is most likely that the patent holder and the researcher will come to an agreement. In connection with this, one must also

point at the possibility to grant licenses on compulsory basis and the research exemption as helpful factors to balance the potential harmful effects of the absolute product patent or a broad patent. They can become extremely handy if the patent holder should choose to exercise his rights strict. The role of compulsory licenses should however not be overestimated, they are hard to come by and rightly so. We do not want the compulsory license to be a negative factor by granting them on too casual grounds. It is important that the first patent holder can count on the incoming licensing fees in order to recoup his expenses or else we might face a legal uncertainty that is not beneficial for anyone. Compulsory licenses should be used as a last resort, and only when absolutely necessary.

It is easy to see how patents on the human genome raise concerns and feelings on a whole other level than most other patents and under such circumstances, it is easy to see why special treatment for the protection of DNA sequences of human origin is demanded. However, is it reasonable to treat human DNA sequences separately from other DNA sequences or other chemical compounds? Alternatively, and perhaps more importantly, is it reasonable to treat human DNA sequences different when so much indicates that the interest in patenting the DNA sequence per se is fading? For all we know, this question might not be an issue in the near future and although we should be careful with our common heritage, it would not be desirable to allow special treatment only on the fragile ground that we have different feelings towards our own genetic material. It is often argued that we should treat human DNA sequences differently because of their multifunctional features, an argument that fail to impress, considering that it is nothing unusual for “ordinary” chemical compounds to have a plurality of functions. These “ordinary” chemical compounds are available for patents and have not caused the controversy it has in the field of gene patents. The feeling you get is that there is something else behind the argument; it feels as though proponents of a purpose-bound protection tries to hide an ethical argument behind a more “technical” argument. I do not imply that ethical argument should not gain relevance in the debate, but one should call something for what it is. To some extent, the same could also be said about the dependency debate. The dependency problems is not something that began with the patenting of human DNA sequences, dependency has been a problem for many years in the pharmaceutical industry, and although the problem is highlighted by many in the pharmaceutical industry, it has not caused the debate we have seen in the field of gene patents.

I believe that to the extent an absolute product protection has negative consequences on research and development, this should be solved without the intervention of the legislator. We have already seen that the patent system is capable of self-regulation in order to deal with the potential problems that might occur. This is not done by introducing a purpose-bound protection, but with a correct appliance of the patentability requirements and the disclosure requirement. Furthermore, by introducing only purpose-bound protection, what is there to say that we will not see a progress resembling what happened in the United Kingdom before 1949, when

product patents were not allowed? With the abolishing of the absolute product patent, creative patentees might nevertheless find their ways round the prohibition making the legislation ineffective.

Some words need to be said about the relationship between the American patent system and the EPC. It is interesting to see that the two systems appear to move closer to each other. We have for example seen that the stricter utility guidelines in the United States have had the effect that both legislations now require a substantial, credible and specific use to be shown for the invention. Although the American patent law and the EPC seem to move in the same direction, there are still some important differences between the two systems. It is probably still harder to meet the patentability requirements in Europe, something that is best illustrated with the different interpretation of the inventive step, where the patenting threshold in Europe is considerably higher. However, an introduction of a purpose-bound patent would mean that Europe would distance itself from American patent law even further, as the absolute product patent is available in the United States. I do not believe this is the right way to go. Instead, we should strive to make the two systems more similar. Patent law today is a global concern, and the number of multinational enterprises expanding abroad is increasing by the year. By having similar patent systems, it would be easier for companies to know what is patentable and what is not.[171]

Although I am arguing that there is no need for introducing a purpose-bound protection on human genes, it is highly interesting, and even to some extent welcome, that France and Germany has decided to deviate from EPO practise. On the one hand, unfortunately outside the scope of this thesis, is the question regarding the validity in Germany and France of the absolute product patents granted at the EPO. On the other hand, this will give us a chance to evaluate the current practise with the EPO under the EPC. Although it might still be too early to calculate the implication the limited protection has had, in a few years time we will probably be able to see the full effect of it. It will be highly interesting to see how the biotech companies in these countries deal with the fact that they cannot obtain an absolute product patent. In terms of investment, my prediction is that we will not see any dramatic differences in the biotechnological field between France, Germany and the rest of Europe. If that were to be true, there is no reason not to allow an absolute product patent when the inventor actually fulfils all the requirements needed to obtain that patent. There is no rationale that when an inventor actually manages to find a novel gene, which is getting increasingly infrequent by the day, he should not receive a stronger protection for his discoveries. Moreover, by finding the new gene, the contribution to the society is potentially greater than discovering new function on an already known gene; the inventor should then be rewarded accordingly by being given a strong protection. It is a quite common

[171] I should point out that I find the European approach to the patentability requirements more suitable than the American equivalency, especially when granting absolute product patents. However, the intent of this thesis is not to advocate a change in American patent law, I will leave that to somebody else.

principle in patent law that “pioneer inventions” are given a broader scope of protection than trivial improvements (provided they meet the patentability requirements), and that should be the case even in the gene patent field.

Unfortunately, until we are able to measure the consequences of having the purpose-bound patent protection instead of an absolute product patent, it is highly possible that the debate will never die, but both sides will continue to repeat the same arguments over and over again, both sides desperately hanging on to their view. Or as the song continues, *“You're right from your side, I'm right from mine”*.

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