Human genes as patents -

Comparative USA and EU legal approach

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Abstract

Inventions made a leap from steam machines to technically modified microorganism and finally genetic inventions took the limelight. In the onset of the age of genetic inventions, human genes were firstly thought to be a non-patentable subject matter however that concept was abolished. As the technology further advances it give birth to express sequence tags or ESTs. They are small sequences of cDNA and extracted with a gene sequencing machine. EST is primarily used as a shortcut in pinpoint only the expressing genes, which are the genes that carry information for the protein synthesis. Unfortunately EST can only locate the expressed gene but it cannot provide any further information about it, in other terms it can locate something for what there is yet no information about its characteristic or function. Subsequently after the NIH's EST patent application is filled it gave rise to a fear that EST will create a patent ticket. General opinion that ESTs patents can get exclusive right over the sequence for which they tag. EST producing companies would have an exclusive right to exclude others from commercially exploit them. This complex situation sparked the desire to further research the probability of ESTs satisfying patentability requirements in the two most biotechnology advanced continents Europe and United States. The methodology would be comparative where ESTs would be compared to patentability requirements prescribed by patent law both of Europe and United States. Previous research conducted by the Trilateral office will be used as the starting point on with an attempt to agree with their findings. Thesis will start with the general introduction on biotechnology, after the overview of the scientific background which will be followed with deeper explanation of EST problem. Analytical part will start with the overview of the European and United states patent law and subsequently each patentability requirement will be assessed individually in connection to EST's probability to satisfy it. With my research I have concluded that findings of EPO and USPTO were founded and with that I agreed with their result.

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Introduction

The positive law is governs itself with the rule that all life is precious, because life is the product of nature and it is not man made, therefore many laws and regulations have been enacted in order to protect what is nature made. Principal rule that governs patent law is to promote the scientific and technical progress by giving a temporary legal protection in exchange for inventors disclosure of the inventive results that she obtained[1].The most recent scientific breakthroughs in area of biotechnology indicate that we are witnessing the dawn of an era new which may, confidently saying, affect and change our standard of living. Especially, by means of new research developments in area such as genetics, which are ought to qualitatively enhance the level of medicine by identification of specific genes that are disease-related, some health-related issues may be efficiently solved by giving an impetus to the pharmaceutical companies to develop drugs that are more effective. Intrigue of biotechnology inventions lies in its unpredictability, today it even asks questions and poses legal problems, which could not even be foreseen by patent law legislators. It is almost truly amazing how development of technology may influence law. Traditionally, patents have been granted only for inventions usually for machines, mechanical process, gadgets but not for biological inventions. The biotechnology industry argues the same point, claiming that its products are biological machines.[2] But what is exactly biotechnology, can

[1] *See* Rob J. Aerts, 'The industrial applicability and utility requirements for the patenting of genomic inventions: a comparison between European and US law', (2004), E.I.P.R. 2004, 26(8), 349-360.
[2] Staking their claim to parts of your body; Biotechnology companies argue that patenting genes stimulates innovation, but others say the reverse may be true, The Independent (London), December 6, 1994, Tuesday Science Page 24.

its notion be defined in a straightforward manner or there is more complexity to it. The first occurrence of the term biotechnology was thanks to an agricultural engineer of Hungarian origin *Karl Ereky*, sometime at the onset of the twentieth century. He defined biotechnology as a work which products often produced from raw materials with the aid of living organism[3]. In somewhat modernized understanding of the term biotechnology, it can be understood as usage of living organisms or their products to modify or enhance human health typically by using the techniques such as gene splicing and recombinant DNA technology[4]. However, through the time meaning of biotechnology had undergo substantive changes due to the development of the technologies that had accompanied the term. These technological breakthroughs gave birth to a result that biotechnology as a science can be divided into three distinct generations.[5] The first generation is the oldest one and it considers techniques as alcohol brewing or other fermentation techniques, it is not quite known when the first traces of biotechnology emerged, but going from the point that humans nature is comprised of its intellectually curiosity by nature it was assumed it appeared early in the human history. The prove lies in numerous findings and excavations, which show many successful attempts of fermentation and scripts about fermentations with the use of microorganisms[6]. Many centuries later, discoveries made by Louis Pasteur in area of microbiology has made an entry to the era of second generation, which afterwards concludes with the mass production of antibiotics. Subsequently, the discovery of DNA structure in 1953 by *James D. Watson* and F*rancis H. C. Crick* represents a beginning of biotechnology in a modern day sense

[3] *See* Graham Dutfield, 'Intellectual Property Rights and the Life Science Industries, a Twentieth Century History', (Ashgate 2003), 135-6.
[4] Linda R. Judge, "Biotechnology: Highlights of the Science and Law Shaping the Industry", 20 Santa Clara High Tech. L.J. 79 (2003).
[5] *See* Graham Dutfield, 'Intellectual Property Rights and the Life Science Industries, a Twentieth Century History', (Ashgate 2003).
[6] See, Robert Bud, History of "Biotechnology"' (1989) 337 Nature 10.

or commonly known as the third generation. Afterwards discovery of the so-called restriction enzymes in 1970 allowed the performance of the world's first gene splicing experiments by Cohen and Boyer.[7] To many this event represents a birth of the genetic engineering or so called recombinant DNA technology.[8] Another discovery, which is important to mention is the identification of the enzyme reverse transcriptase.[9] The importance of this enzyme lies in its ability to allow for the molecule of the RNA to be converted into the molecule of DNA, by which scientist were able to further utilize cloning and other genetic manipulations. These technologies further allowed for the development of the more sophisticated biotechnology techniques such, genome manipulation, tissue engineering etc. The period where there was another tremendous up rise in biotechnology was from 1980 to 1990 in where the automated gene-sequencing machine was invented by Leroy Hood in 1981. Today a certain category of biotechnology plays an important role in commercialization of genetic inventions, that category is known as the genomics, which is comprised of mapping, sequencing and analyzing the genome (full set of genes) of any complex organisms.[10] Naturally, the biggest light for doing the genomic research fell onto the human genome. For that reason the Human Genome Project (further HGP) an international public endeavor, was set out in 1990 with a goal to determinate the sequence of nucleotide base pairs that builds up the human DNA, and to identify and map all of the genes of the human genome. Even thou this project has been run by the reputable scientist from every part of the globe, due to potentially immensely large amount of work research to be done and cost to be covered the

[7] *See*, Linda R. Judge, 'Biotechnology: Highlights of the Science and Law Shaping the Industry', 20 Santa Clara High Tech. L.J. 79 (2003).
[8] Ibid.
[9] D. Baltimore, RNA-dependent DNA Polymerase in Virions of RNA Tumour Viruses, 226 NATURE 1209 (1970); See H.M. Temin & S. Mizutani, RNA-dependent DNA Polymerase in Virions of Rous Sarcoma Virus, 226 NATURE 1211 (1970).
[10] Graham Dutfield, "Intellectual Property Rights and the Life Science Industries, a Twentieth Century History", (Ashgate 2003).139-140.

debating question of priority, what should be done first was created. The controversial answer that had arrived to the asked question was not in the shape of what aspect of the project will get the advantage over another, i.e. whether to find genes first and to conduct the sequencing later or vice versa, rather it arrived in a shape of a new method. This method was for the first time used by Craig Venter, it was a "shortcut method of identifying genes using the so called express sequence tags (EST)"[11] with the use of DNA sequencing machines. Biotechnology definitely has the potential to become one of the most assuring technology frontier in the upcoming decades[12] **.** Is biotechnology only important for advancing our understanding what are the key foundations for building life? Not so, biotechnology inventions and breakthroughs may easily find their further application in other related fields of industry such as medicine, pharmaceutics agriculture, green energy etc. Biotechnological inventions maybe used discover treatment for gene related disease, to prevent occurring of some genetic deformations, assist pharmaceutics industry to manufacture better and more personalized medicine, enhance the durability of crops or even clean the oceans from oil spills. Nevertheless, in order to strengthen their position on the market and not to compromise all of their research and inventions, companies that are fully oriented in developing biotechnological inventions needs to shield what they know and what they made from competitors. Foremost biotechnology represents a specific area of technology industry and as it heavily relies on research but also as any other industry it needs funding. In order to make their research easier to bear biotechnology oriented companies need to develop a solid patent portfolio.[13] Companies which are primarily oriented to biotechnology are usually start-up companies. As any other startup they start with an idea which in most cases has not been transformed in a product that is ready to

[11] Ibid.
[12] European Commission, Life Sciences and Biotechnology – A Strategy for Europe, 2002.
[13] Eric K. Steffe and Timothy J. Shea, Jr., 'Protecting innovation in biotechnology startups', Published online: 23 June [2003], Nature.com, https://www.nature.com/bioent/2003/030601/full/bioent741.html , accessed 06.04.2018.

be sold. In order to further develop their product biotechnology startups needs to attract capital, which will allow them to cover the costs of the imperious research which cannot rarely cross six figures with an ease. When capital investors search for its new portfolio they search for something steady, in case of biotechnology startup it will be a granted patent over its invention. Patenting their invention biotechnology startups can generate others income such as royalties that they will collect from their licensees.[14] Concluding patents play major role in biotechnology industry. Due to that biotechnology companies are in everlasting contest with patent office where they are applying. Biotechnology inventions as they started to be filled for patenting had many steep hills to cross. Are they moral, are they useful are they inventive are they new are one of the many obstacles that a biotechnology patent claim needs to pass while being examined by the patent office. Scenario where a biotechnology company discover a way around all of that undue research that is needed and obtain patent faster than its competitors is a scenario where a fear of those patent claim overflowing the market can have its ground.

[14] Ibid.

Chapter 1. Technical background

Intellectual property law is a branch of law that is closely related to the subject matter which it's regulated by it. A telling explanation could be seen in relation between criminal law and the criminal mind. Also Due to the fact that patents and satisfaction of their requirements need to be analyzed in a close manner with the characteristic of the invention for which patenting a prospective patentee is applying in this section I will provide with the basic scientific explanations which will cover the substantive material of the invention. This will be conducted in a logical block by block way, starting from the first notion such as DNA and further explaining what is EST concluding with their alleged issue. Deoxyribose Nucleic Acid or DNA is the carries all of genetic information for any complex organisms.[15] DNA comprised of two linear, non-branching polynucleotide strands shaped as double helix, which are in-between each other held together by hydrogen bonds, those bonds are connecting purine and pyrimidine(type of nucleotide bases) bases which are reaching out inwards from the two backbone chains of the both polynucleotide strands.[16] In nature there are four type of nucleotide bases, which could be found in a DNA: deoxyadenosine (*A*), deoxythymidine (*T*), deoxyguanosine (*G*) and deoxycytidine (*C*). Gene represents a specific sequence of nucleotide bases, which are playing the role of carriers for the set of instructions, which are required for protein construction.[17] RNA or better known as ribonucleic acid a linear polymer that is composed of nucleotides. The purpose of RNA lies in delivering the instructions which is encoded inside of the DNA. That genetic information plays an important role which for

[15] Melanie J. Howlett ,Andrew F. Christie, "An analysis of the approach of the European, Japanese and United States Patent Offices to patenting partial DNA sequences (ESTs)", [2003] , IIC 2003, 34(6), 581-602.
[16] Leslie G. Restaino, Steven E . Halper n and Dr. .Eric L. Tang, "Patenting DNA-R elated Inventions in the European Union, United States and Japan: A Trilateral Approach or a Study in Contras t?", 2002 Brown Raysman Millstein Felder & Steiner LLP.
[17] *See* Melanie J. Howlett ,Andrew F. Christie, "An analysis of the approach of the European, Japanese and United States Patent Offices to patenting partial DNA sequences (ESTs)", [2003] , IIC 2003, 34(6), 581-602.

biological activity the proteins will conduct after their synthesis. For that reason the accurate synthesis of proteins thus is critical to the proper functioning of cells and organisms.[18] Proteins are large and complexly built molecules, theirs composition is made of amino acids and are essentially used for the structuring, functioning, and regulating of life processes.[19] However, the sequence order of the amino acid, theirs specific order in side of the protein is going to determine what exact function a fully synthesized protein is going to have. Now as it can be seen from the above-mentioned, genes plays an activator role in the protein production, which is done by combining them in various sequences. Other thing that is important to mention about genes is their structure, that they are comprised from two main parts, a non-protein coding region called the intron and the coding protein region called exon[20]. In order for a cell to produce proteins, the genetic information from a gene is copied into new strands of messenger RNA (mRNA), in process called transcription or gene expression. As a process Gene expression represents a way which information is coming from the genes are used in the synthesis of a functional gene product. This process is fundamental because by it the genetic information stored in DNA is interpreted and the properties in the expression are going to give rise to the organism's observable characteristics which is called the phenotype. Phenotypes are expressed by the synthesis of proteins that control the organism's shape or that act as enzymes, which are catalyzing certain metabolic pathways characterizing the organism. Thus, for the development of any multicellular organism gene expressions is crucial. The composition of the amino acids is then being directed from the mRNA,

[18] Leslie G. Restaino, Steven E. Halpern and Dr. Eric L. Tang "Patenting DNA-Related Inventions in the European Union, United States and Japan: A Trilateral Approach or a Study in Contrast?" 2002 Brown Raysman Millstein Felder & Steiner LLP.

[19] Encyclopedia Britannica, Daniel E. Koshland Felix Haurowitz, 'Protein', https://www.britannica.com/science/protein , accessed 06.04.2018.

[20] Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', 2017, Edward Elgar Publishing, 63-67.

which will later allow for a complete protein assembly[21]. The mRNA of a certain organism can be isolated by technical means and afterwards copied in a complementary or cDNA sequence[22].A cDNA is a cloned counterpart of the DNA that is used as the technique which will allow for expression of the certain protein that is not normally expressed in that cell.[23] This is isolation is important due to the fact that, in a situation where there is a discovery that an organism is able to produce a certain protein which could be useful for some other utility not just the one that is coded, then by this isolation technique that protein is being isolated to just fraction of amino acids which will further aid geneticists to determine which potential gene is coding for that protein. Once the identification is been made with the above-mentioned process for the aimed gene, then the desired protein can be produced by a technical mean. Nevertheless, sometimes this process is not very straight forward, as I have mentioned the concrete sequence of amino acids need to be determined in order to locate a gene that codes for a wanted protein. The entire human genome is comprised of roughly speaking amount of 100.000 genes, luckily only in the so-called coding areas of the DNA is where the exons the part of the gene that carry protein coding sequences are located. As an aid in locating those protein-coding genes, EST which stand for express short sequence tag of a cDNA, can be used only to identify the coding part of genes.[24] Expressed sequence tags (ESTs), which are portions of identified genes in the cell while the particular gene is being expressed[25]. Their importance lies in their ability to identify a corresponding gene. Whit these geneticist are able to discover a new gene but with one drawback, which is EST inability to disclose biological

[21] Melanie J. Howlett ,Andrew F. Christie, "An analysis of the approach of the European, Japanese and United States Patent Offices to patenting partial DNA sequences (ESTs)", [2003] , IIC 2003, 34(6), 581-602.
[22] See, Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', 2017, Edward Elgar, 65-67. Publishing, Lander and others (n 2), David L Lockhart and Elisabeth A. Winzeler, 'Genomics, Gene Expression and DNA Arrays' (2000) 405 Nature 827, Watson 'Molecular Biology of the Gene' (n 4) 467-468.
[23] Human Genes.org, 'cDNA (Complementary DNA), http://humangenes.org/cdna-complementary-dna ,
[24] Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', 2017, Edward Elgar Publishing, p-65.
[25] John H. Barton, 'United States law of genomic and post-genomic patents', [2002], IIC 2002, 33(7), 779-789.

function of that particular gene. The process for obtaining the EST, is only available thanks to the certain enzyme called reverse transcriptase which allows for the mRNA to be converted back into the DNA. As a result we get a complementary DNA or cDNA and it has it has basically the same gene sequence order just the non-coding part of the genes introns, or more informally called junk DNA are not present.[26] Further ahead by using the sequencing technique on cDNA, geneticists are able to obtain the partial gene sequences the so-called EST.[27] The use of ESTs may be seen from a few different perspectives. EST can be used as marker "genes actually transcribed in vivo; they point directly to the expressed gene"[28].For that use, they are suitable to be probes which may locate the certain gene and even discover what is the biological function for the underlying protein for which the found gene codes.[29] Other potential use of EST lie in their applicability to serve in forensic analyses, tissue specific or individual-specific identification, and in understanding and curing gene related disease. [30]

[26] Graham Dutfield, "Intellectual Property Rights and the Life Science Industries, a Twentieth Century History", (Ashgate 2003). P-140.
[27] Ibid.
[28] Andreas Oser, 'Patenting (partial) gene sequences taking particular account of the EST issue', [1999], IIC 1999, 30(1), 1-18.
[29] Ibid.
[30] Ibid.

Chapter 2. Decoding the EST problem

This chapter will be dealt with two things. Firstly some basic notions of the patentability requirements will be explained, afterwards an overview of the EST problem will follow. Before explaining the issues that surround EST patent claim, I it will be necessary will to first explain the state of the art when it comes to granting a patent over genetic inventions patent claims. Any patents claims for genetic invention in order to be granted a patent from the prospective patent office where the patentee is applying in any jurisdiction must satisfy the basic patentability requirements. Patent can be defined as an agreement between the government and an inventor (patentee) under which, in exchange for the inventor's complete disclosure of the invention to the public, the government will bestow the inventor with an exclusive negative rights [31]. This rights amount to excluding others from making, using, selling or offering for sale the claimed invention for a certain limited period of time. Different jurisdictions have their own different periods for which the patent is granted, but the period is mostly around 20 years, after the witch the inventor's rights subside. The practical aims of a patent grant is to reward the inventor for the diligent work and hers contribution to the society, but also to coats the scientific progress with competitive edge which is generally done through the commercialization of technologies.[32] Despite that, patents may develop an anti-competitive aspect, due to which immense diligence and even maybe strictness is required in patent clam examination procedure by patent office. Awarding patents

[31] Leslie G. Restaino, Steven E. Halpern and Dr. Eric L. Tang "Patenting DNA-Related Inventions in the European Union, United States and Japan: A Trilateral Approach or a Study in Contrast?" 2002 Brown Raysman Millstein Felder & Steiner LLP.

[32] Denis Schertenleib, 'The patentability and protection of DNA based inventions in the EPO and the European Union', [2003], E.I.P.R. 2003, 25(3), 125-138.

easily for inventions that should not receive them may generate a negative impact in the certain industry, in this case biotechnology and genetic inventions, which in the end allow for those patent holders to acquire monopolistic position. As it goes for the patentability requirements, four requirements can be differentiated even together that different jurisdictions maybe name them differently and occasionally slight differences may be established. Those requirements are that the substantive matter of the concrete invention must be patentable, in other words not to be excluded from the patentability. For example stipulation of this requirement can be seen in the text of Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in article 27 (2) and (3). Additionally inventions are going to be excluded from patentability if they consider discovery of material that can be already found in nature then scientific theories, business and mathematical methods flora and fauna other than microorganisms, solely mental acts or playing games, any method for treating of humans or animals including diagnostic methods practiced on humans or animals with exclusion of tools and products for that particular use.[33] Accordingly, to the so referred product of nature doctrine there is an exclusion of patentability for anything that is considered to be a physical phenomenon or that can be found in nature in the condition in which the invention is.[34] The underlying argument in this doctrine was that patent claim for something that is already out there in nature, constitutes just a discovery, which is not an invention. This issue was posing to a problem for some time to gene patent claims; nevertheless case law regarding this subject has changed the light of the understanding things. In the case of *Amgen, Inc. v. Chugai Pharmaceutical Co*[35] in a summary the patent claim was for clone, or cDNA version of a naturally-

[33] World Intellectual Property Organizatio, 'Wipo Intellectual Property Handbook', [2004], WIPO PUBLICATION No. 489 (E).
[34] John M. Conley, Gene Patents and the Product of Nature Doctrine, 84 Chi.-Kent. L. Rev. 109 (2009).
[35] John M. Conley, Gene Patents and the Product of Nature Doctrine, 84 Chi.-Kent. L. Rev. 109 (2009); 927 F.2d 1200 (Fed. Cir. 1991).

occurring eritroprotein gene (EPO), which has the same function as his naturally occurring equivalent is different from it due to the missing intron part of the gene.[36]The crucial fact in this case was that to the intellectual legal doctrine genetic material is regarded as chemical compound and by the way that inventor got a EPO, by means of the isolating it, that compound is patentable and does not succumbs under the products of nature doctrine, due to the fact that it was made by man and by a technical mean. Similar situation developed in *Myriad case* in where the court concluded that naturally occurring genes are not patentable but the cDNA is. The second patentability requirement is industrial application/utility requirement. This means that invention needs to have a certain practical purpose, not matter if the patent claims is for patent represents a practical result or for a process. Patent claims for EST are encountering a substantial obstacle regarding this patentability requirement, more about this issue will be explained in subsequent chapters. The requirement of inventive step or non-obviousness, means that the process with which the inventor has come about with hers invention must not an obvious process to a person that is normally or ordinary skilled in the perspective science. Regarding the level of skills that the ordinary person needs to possess, it is generally agreed that it evolves a person with an average skill and knowledge and not an expert level professional[37]. There are many allegations that EST and claims arising from then do not include inventive step, that the process for obtaining them is to obvious. In later chapter, we will see how prospective offices and case law deal with this issue. Other patentability requirement, which is in a close bond with non-obviousness, is the novelty requirement. This requirement is satisfied is the claimed invention is different and not predicted

[36] John M. Conley, Gene Patents and the Product of Nature Doctrine, 84 Chi.-Kent. L. Rev. 109 (2009); Also For a more detailed review of the science of DNA patents, see Conley & Makowski, supra note 7, at 309-16.
[37] World Intellectual Property Organization, 'Wipo Intellectual Property Handbook', [2004], WIPO PUBLICATION No. 489 (E).

by 'prior art'[38] of an industry. As I mentioned above the connection between non-obviousness and novelty is that without the latter, the former did not have an inventive idea, a certain jump in thinking which result with an invention that is different from the prior art. Final patentability requirement is of a rather formal legal nature than substantive, it is the requirement of the inventions disclosure. The simple explanation is not enough to satisfy this requirement, the claimed inventions needs to sufficiently described as to its substantive part, its alleged practical use and in a manner that it disclosure is clear to the ordinary person skilled in the art.[39]As it is realized form the stipulations above, the invention relating human genes can be patentable if they are isolated by technical means, if the invention is new, different from prior art, the invention is a resulted from an inventive step, that it has a specific practical purpose or a function and finally that invention its self, instruction on how to use it and manufacture it are sufficiently explained so that a persons with an ordinary skill in art may understand it and use it. As I mentioned in the previous sub chapter what are ESTs and the potential benefit that they could give to the genetic scientist. Human Genome project was only the first part of the saga that stir up the public debate regarding the EST and their patentability and the effects of that debate are still felt today. However the precise event that had started everything occurred in June 1991 when a patent application which was filled on the behalf of the United States National Institution of Health (NIH), which was covering cDNA and ESTs.[40]Although this patent application never became public, however going from Marta Diaz Pozo's research the claim contained about 6800 partial cDNA sequences, around 340 EST and their protein products included.[41]For the both claim in the application, it as stipulated that they

[38] Ibid.
[39] Ibid.
[40] See, Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', [2017], Edward Elgar Publishing, p-70..
[41] Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', [2017], Edward Elgar Publishing, p-70.

have a practical use, which was made of several other utility's, such as gene location marker and tissue typing tool. By following this it was obvious to the scientific community that the prime tool that the scientist at NIH were using was a rapid screening technique over a large numbers of DNA sequences to randomly sequence and locate human genes, unfortunately without the information for what protein is the located gene coding for.[42] NIH patent applications has been confronted with severe critics and concerns from the scientific community and Human Genome Project organizations as well. In 1997 the Human Genome Organization (HUGO) has published their statement in which they stated that this type of patent claims that NIH filed for inventions of uncertain purpose poses a great chance of making further research excessively depend of such type of patents.[43] Those critics and the public outcry was to some degree successful, as NIH later on abolished its patent claims. Nevertheless HUGO's fear was derived from the idea that patent claim that covers EST, will accompany any new gene that were found by use of EST, any proteins that are encoded by those gens even the antibodies that can be further developed from them[44].This can further establish that companies who file patent claim for ESTT can become dominant subject in the market. Despite the NIH unsuccessful patent claims, in the following years genetic research companies such as Celera Genomics, Incyte had filled more than that tens of thousands over EST, in the faith that if the patents are granted over their claims they would be able to exclude others to commercially exploit research on the newly located genes.[45]

[42] Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', 2017, Edward Elgar Publishing, p-70, Stephen B. Maebious, 'Novel DNA Sequences and the Utility Requirement: The Human Genome Initiative', (1992) 74 JPTOS 651.
[43] Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', 2017, Edward Elgar Publishing,70-73.; HUGO Intellectual Property Committee Statement On Patenting Issues Related to Early Release of Raw Sequence Data (May 1997).
[44] Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', 2017, Edward Elgar Publishing 70-77.; Davis and others (n 40).
[45] Ibid; Cockburn (n 21), 112-113.

But why EST patent claim posed such a problem, why did the attempt of patenting them inspire such a commotion? Several issues can identify the EST patent claim. Starting from the requirement of inventive step the technique used lacked an inventive step it was categorized as routine job, even thou that DNA sequencing technique can be time consuming. Other issue is on connection to allegations that patent claims for EST were without industrial applicability/utility requirement. Said in a more plain language main claim of the EST use was in their ability to locate the location of a protein-coding gene. Regardless of the fact how useful the ability, of expressed gene's location is EST does not uncover the characteristics of the discovered gene, neither the biological function of the connected protein found. So principally EST patent claim only amounts to finding a gene for which of the moment of finding there is no know use, in this situation EST only amounts to be used as a probe to discover something, which use or purpose will not be known at the moment of that discovery. Discovered gene will certainly contain the genetic information for protein manufacture, but in order to discover that allegation further research is need to be conducted probably with implying more intellectual effort and time.

However even with array of issue concerning ESTs, their utilization cannot be disregarded so easily. Even for merely hypothetically, ESTs may demonstrate their application as "biochemical probes or generally research tools"[46], "for forensic identification, tissue type or origin identification, chromosome mapping and identification and to tag a gene of known and useful function"[47]. In correlation to this generally speaking many biotechnology companies that are using EST s in their research, continuously to emphasize that their work needs to be protected at an early stage, when concrete use for their claimed invention still needs time to be disclosed, but evidence

[46] Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', 2017, Edward Elgar Publishing 73; Davis and others (n 40).
[47] Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', [2017], Edward Elgar Publishing 73; Dorothy R Auth, 'Are ESTs Patentable?' (1997) 15 Nat Biotech 911.

that the discloser will indeed be possible is present.. They base their argument in the genes limited direct application and that in most cases further research is needed, with patent granted at this stage the companies filling the patent application for ESTs can bolster their position on the market[48]. By doing that they will attract much more needed investments, which later going to additionally develop the patent, due to which other connected industries such as pharmaceutics industry can benefit greatly[49]. The benefit of this chain of event due to EST patent can be seen clearly. The fact that something what was considered to be almost ordinary at the beginning such as ESTs could create this amount of attention I must comment that it is amazing at least. Their future significance can go take on both ways of the path, the one of abolishment or one that will take overall biotechnology science to another level and with that probably make notable changes in intellectual property law and its policy. Because of this uneven ground regarding ESTs, despite the research done so far, in this thesis I am going to examine what is a probability that ESTs be granted with a patent. Going from the fact that after above-mentioned NIH event many companies around the globe had filled patent claims regarding ESTs, I will narrow my research onto the United States and European Union jurisdiction primarily. I choose those jurisdiction due to their developed patent law, case law regarding the matter and being the two jurisdictions with the most developed biotechnology industry. In slight occasion, I will also refer to Japans jurisdiction, but only in a cursor matter, this will be done due to evolvement of the Japans patent office (JPO) in a joint Trilateral between EPO, USPTO and JPO study which I will use as a basis for my research. The methodology of research that is going to be used in this theses is going to be of comparative nature, for the reasons that comparative approached may set out the peculiarities of each jurisdiction on

[48] Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', [2017], Edward Elgar Publishing 72-4.
[49]Ibid; Margaret Liewelyn, 'Industrial Applicability/Utility and Genetic Engineering: Current Practices In Europe and the United States', (1994) 16 EIPR 473.

the basis of which the similarities and differences, specific advantages and disadvantages may be underlined. In subsequent two chapters, I will research how the substantive matter of a EST correlates with the both jurisdictions patentability requirements. In the first following chapter, I will examine EU's patentability requirements, but before that I will provide with explanation of EU's legislative framework when it comes to patentability of genetic inventions. At the end of this chapter, I will provide with a chapter conclusion. In the second chapter I will undertake the same approach, where first I will explain the United States legal framework regarding patents and afterwards investigate its patentability requirements for the genetic inventions and how they co relate with patentability of ESTs, the chapter will end with in chapter conclusion as in the former chapter. The last chapter will be my final conclusion regarding patenting EST in both jurisdictions, concluded with possible future remarks. The aim of this thesis will be an attempt to successfully apply other possible reasoning's that could bring the same result as the three patent offices concluded in their research in context could EST satisfy the patentability requirement in Europe, United States and Japan.

Chapter 3. Legal framework

In this chapter there will be a basic explanation on how is patent law regulated in Europe and United States. European patent law will be first where there will be overview of European Patent Law and Directive 98/44/EC on the Legal Protection of Biotechnological Inventions or famously known as the Biotech Directive. Before explanation of the most important provisions from both legal acts, there will be explanation on what kind of connection they have. Afterwards there will be the explanation of the United States patent law where the attention will primarily have U.S.C 35.

3.1 European patent law

European Unions' patent law is probably one of the most complicatedly regulated one. It is basically regulated by four different legislations. Starting from the international aspect international patent treaties, such as the TRIPS, PCT, Paris convention, have established the legal base for further development of the Unions patent law. From the other perspective, the EPO grants patents according to the EPC, which is a multilateral treaty currently in force in 38 countries. After the patent is granted the national effect of the countries were patent protection is sought take over the wheel and further the Biotechnology Directive, which has an effect on the way European

patents are assessed if they are claims for biotechnology patents.[50] In other words, despite the fact that the substantive regulation of the EU patent law falls on the Directive 98/44, all the process regarding the patent application, filling, examining, opposition is guided by the European Patent Office, which is guided by a non EU legal instrument the European Patent Convention.[51] As way of harmonization, The European Patent Organization implemented the provisions of the Directive into the Implementing Regulations of the European Patent Convention. Provisions of the Biotechnology's Directive, which postulate particular patentability requirements for biotechnological inventions, were transferred literally into the text of the EPC.[52] Namely those provisions of the Directive were taken from the Chapter 1, which regulate the patentability of the biotechnological inventions.[53] Nevertheless those provisions of the directive that were transplanted into the EPC, were enacted using EPC and established case law as a model. The Implementing Regulations of the EPC, more precisely their original wording had to be revised for the sake of EPC's patentability provisions continue to be interpreted in line with the Directive.[54] Also, a rule was inserted which provides that the Biotechnology Directive "shall be used as a supplementary means of interpretation" of the EPC. This is stated in the EPC 2000 Rule 26 , where says that for all biotechnology inventions and those inventions applying for the European patent The Biotech Directive will be used as an additional means of interpretation.[55]

[50] Timo Minssen ,David Nilsson 'The industrial application requirement for biotech inventions in light of recent EPO & UK case law: a plausible approach or a mere "hunting license"?, 2012, E.I.P.R. 2012, 34(10), 689-703.
[51] Rob J Aerts, 'Biotechnology patenting caught between Union law and EPC law: European bundle patents, unitary patents and intentional harmonization of decisions in the internal market', Queen Mary Journal of Intellectual Property, Vol. 6 No. 3, pp. 287–303.
[52] Ibid; Notice dated 1 july 1999 concerning the amendment of the Implementing Regulations to the European Patent Convention OJ EPO 8-9/1999, 573-582; EPC rr. 26 to 29.
[53] Dr. Franz Zimmer, 'New Rules of the European Patent Office for Biotechnological Inventions', www.grunecker.de/files/biorules.pdf . Accessed 04.02.2018.
[54] Ibid.
[55] EPC 2000 Rule 26 (1).

3.2 European Patent Convention

European patent legislation had a three-step development throughout the history. Historically speaking first significant international convention that regulated patents in Europe was the Paris Convention in 1883. Despite that the major focus of this convention was not patent law, however it left a role model for other international patent law treaties. Many legal institutes introduced in it have a pertinent relevance even in today's EU patent law.[56] Following it was the Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, which was signed in 1963. The Idea for The Strasbourg Convention was brought up from the need to unify the European patent law more concisely to unify Europe on both procedural and substantive requirements of patent law.[57] Importantly Strasbourg convention formed the basis for the upcoming European Patent Convention (EPC) also recognizable under the name of Convention on the Grant of European Patents. After some years of setbacks and negotiations it was finally signed in the year of 1973, in Munich[58]. EPC can be understood as an intergovernmental treaty with its members that encompass country that are beyond the Economic Community[59].However the EPC from 1975 had undergo some revisions and afterwards become know was the EPC 2000. Nevertheless, it's given name 'European' the EPC is a product of Council of Europe's initiative due to which it is not the part of the European Union's legislation

[56] Michael LaFlame, Jr.' The European Patent System: An Overview and Critique' Online journal www.hjil.org/articles/hjil-32-3-laflame.pdf ; Gerald Paterson, 'The European Patent System: The Law and Practice of The European Patent Convetion' 11 (1992).
[57] Michael LaFlame, Jr.' The European Patent System: An Overview And Critique' Online journal www.hjil.org/articles/hjil-32-3-laflame.pdf ; PATERSON, supra note 33, at 15. Accessed 04.05.2018.
[58] Catherine Seville, 'EU Intellectual property lad an policy' [2009]. Edward Elgard Publishing, 92-93.
[59] Catherine Seville, 'EU Intellectual property lad an policy' [2009]. Edward Elgard Publishing.92.

therefore European Union does not have jurisdiction over it. EPC formed the European patent organization, which further consists of European patent office (EPO) which has a function of examination and granting the European patent. EPC 2000 has set up a solitary and highly centralized patent granting system.[60] Hence that it would be wise to mention that European patent should not be understood as a unitary patent, but more a bundle of patents made up from countries where the applicant seeks to get the patent. In other terms, when a patentee files for the patent application at the EPO she will disclose in which particular country she wants her invention to be granted a patent. "This concept is generally called a "*bundle of patents.*"[61] What this means is that that with granting a European patent that patent will be regarded as a national patent in each state for which the applicant is filling for.[62] However a certain fee, which is currently around 80 euros needs to be paid for each country that the applicant decides to seek patenting in[63]. Any natural or legal person, or anybody equivalent to a legal person, regardless of their nationality and place of residence or business, may file an application for the European patent. . European patent application is consisted of a request for the grant, a description of the invention, one claim or sometimes more than one, drawings that are connected to in the description or claims, and an abstract.[64] Patent application, which is also known as 'EPO Form 1001' from which is obtainable free of charge, together with explanatory notes, from the EPO and from national industrial property offices. The European patent application need to have a designated inventor, if the applicant is not the inventor or is not the sole inventor, in that case applicant must file the designation of the

[60] Ibid.
[61] Michael LaFlame, Jr.' The European Patent System: an Overview And Critique' Online journal www.hjil.org/articles/hjil-32-3-laflame.pdf accessed 06.04.2018. 613.; Paterson supra note 33, at 20.
[62] Catherine Seville, 'EU Intellectual property lad an policy' 2009. Edward Elgard Publishing; EPC 2000 Art 2. Art 64.
[63] Catherine Seville, 'EU Intellectual property lad an policy' 2009. Edward Elgard Publishing.92-96.
[64] Annette Kur, Thomas Drier 'European intellectual property law, text cases and materials' [2013] Edward Elgar publishing.

inventor in a separate document, of course with connection applicant rights from the claimed invention.[65] The application needs to be filled for the EPO which is located in Munich, Germany. Beside this way of filing a patent claim a prospective applicant may as well file a patent claim through the national office of the EPC contracting state, which will result in further forwarding of the application to the EPO.[66] The patent claim needs to have a concisely defined matter for which protection is being sought.[67] Type of claims that can be applied for are product claims, process claims and the so called 'product by process claims'[68]. When the patent is granted its durations is 20 years from the filling date.[69] Other dominion of the EPC 2000 is that unlike the application for the previous EPC, application for a patent could be filled in any language due to the reason that the claims translation into the EPC official languages (English, French, and German) is only needed at the later phase of the EPO proceedings. [70] Calling EPC an advantageous system could be seemed as an understatement. But that was not envisioned in the first place. As *Vincenzo Di Cataldo* stated in his famous article *From the European Patent to a Community Patent,* "EPC was a tool, which should have only a partial effect regarding harmonization of the EU patent law." Nevertheless, EPC 2000 regulates the substantive law of the European patent, firstly going from the article 52 (1) where is stated that European patent shall be granted for any invention, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of

[65] How to get a European patent, Guide for applicants, April [2004] (10th edition), https://www.obi.gr/obi/Portals/0/ImagesAndFiles/.../g1en_net.pdf , accessed 06.04.2018.
[66] EPC 2000 Art 75.
[67] EPC 2000 Art 84.
[68] EPC 2000 Art 63; Catherine Seville, 'EU Intellectual property law and policy' [2009], Edward Elgard Publishing, 96-97.
[69] Catherine Seville, 'EU Intellectual property law and policy' [2009], Edward Elgard Publishing 94-93; EPC 2000, Art. 63.
[70] European Patent Convetion 2000 Article 14 (1), (2); Catherine Seville, 'EU Intellectual property lad a policy' [2009]. Edward Elgard Publishing,

industrial application.[71] Unfortunately the EPC does not explain directly the term invention and what does it stands for, however it could be concluded that explanations has been done in an indirect way in EPC Art. 52 and 53. Art 52 of the EPC gives an exhaustive list what is not and cannot be held as an invention, therefore discoveries, scientific theories and mathematical methods also aesthetic creations, schemes, rules and methods for performing mental acts, playing games or doing business, programs for computers and presentations of information.[72] This article plays an essential role, because it regulates which types of inventions cannot be patentable.[73] Foremost in article 53 of the EPC it is stipulated that certain inventions are momentarily excluded for the patentability, such inventions are: inventions which commercial exploitation that could be held as contrary to '*ordre public'* or morality then plant or animal varieties or essentially biological processes for the production of plants or animals, any methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body[74]. Other EPC articles will be addressed in later chapters.

[71] European Patent Convention 2000 Art 52 (1).
[72] European Patent Convention 2000 Art 52.
[73] Catherine Seville, 'EU Intellectual property lad a policy' 2009. Edward Elgard Publishing 78-80
[74] Catherine Seville, 'EU Intellectual property lad a policy' 2009. Edward Elgard Publishing, 80; European Patent Convention 2000 Art 53 (a), (b), (c).

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

Considering how biotechnology and genetic engineering rapidly develops and that their role in many other connecting industries is not getting smaller, only builds up on the importance of genetic inventions. The Directive 98/44/EC on the legal protection of biotechnological Inventions or less formally known as the Biotech Directive aimed primarily to harmonies legal protection of biotechnological inventions.[75] Despite its valuable aim, it's enacting had a turbulent history. There were several attempts to achieve legal harmonization in the EC with the above mentioned directive. The first attempt was undertaken in the 1988, however the then present general current regarding the patenting biotechnological inventions proved too much to bare, due to which it first proposal for the directive was finally rejected in 1996 by the EU parliament.[76]Finally directive was adopted in 1998. The Directive is divided into the five chapters in which chapter one deals with patentability, chapter two with scope of protection, chapter three

[75] Directive 98/44/EC of the European Parliament and of the Council of July 1998 on the legal protection for the biotechnology inventions, [1998] OJ L 213/3 (Biotech Directive); Annette Kur, Thomas Drier 'European intellectual property law, text cases and materials' [2013] Edward Elgar publishing 50-59.

[76] Annette Kur, Thomas Drier 'European intellectual property law, text cases and materials' [2013] Edward Elgar publishing; Proposal for the council directive on the legal protection on the biotechnological inventions, COM (1988) 496 final, Available at http://aei.pitt.edu/3814/ .

deals with compulsory cross-licensing, chapter for with depositing of biotechnology inventions and chapter five is contained of specific final provisions.

Article 3 (1) sets out the requirements which an invention should satisfy cumulatively in order to be granted a patent. "Inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used."[77] Following that Art 3 (2) stipulates that even biological material, which is normally found in nature, can also be patented if that same material is isolated or made by technical process.[78] Article 5 (1) specifies that "human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions."[79] In connection to that article 5 (2) states "an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."[80] It can be seen that legislators wanted to stress the importance of the isolation by technical means, due to the fact that it respects a necessary step to differentiate between what is a discovery, which is something that can be already found in nature and as that it cannot be patentable and what is an invention. Moving on Article 6 where it contests that inventions in certain situations shall be considered non-patentable. Moreover i.e. explained that situations in which the commercial exploitation would be contrary to *ordre public* or morality, however, that does not mean that

[77] Directive 98/44/EC of the European Parliament and of the Council of July 1998 on the legal protection for the biotechnology inventions, [1998] OJ L 213/3 (Biotech Directive) Art. 3 (1).
[78] Ibid art 3 (2).
[79] Ibid art 5 (1).
[80] Ibid art 5 (2).

commercial exploitation is not going to be considered as contrary to public order and morality if it is prohibited by the national law where the patent application is filed for.[81] Article 6 (2) expresses that processes for cloning human beings, processes that modify the genetic identity of human beings, uses of human embryos for industrial or commercial purposes, processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes are non-patentable.[82]

3.4 United States patent law

The United States patent law, is not that hectically regulated as its counterpart across of the Atlantic. Mainly it is regulated by the United States Code Title 35. By the U.S. Constitution, The Congress shall have the power to grant progress of Science and useful Arts, by manner of granting the exclusive rights to its authors and inventors to a specific duration of time.[83] On the other side United States being a country that recognizes the legal importance of precedent law, it has a very important role of further explaining the practical application of the legal provisions which are stipulated inside of the USC 35. In a very telling example the aim of the United States patent law may be observed "Achieving the ultimate goal of a patent involves, to use an analogy, having the separate keys to open in succession the three doors of [35 U.S.C.] sections 101, 102, and 103." as Judge Giles S. Rich stated.[84] This implies that a prospective patentee in order to get a patent granted

[81] Directive 98/44/EC of the European Parliament and of the Council of July 1998 on the legal protection for the biotechnology inventions, [1998] OJ L 213/3 (Biotech Directive); Art 6. (1).
[82] Directive 98/44/EC of the European Parliament and of the Council of July 1998 on the legal protection for the biotechnology inventions, [1998] OJ L 213/3 (Biotech Directive); Art 6 (1).
[83] United States Constitution, Chapter 1, article 8.
[84] Giles Sutherland Rich (1904-1999) was the oldest active federal judge in U.S. history. Patent and Trademark Office Mourns Death of Judge Giles S. Rich (last modified July 1, 1999http://www.uspto.gov/web/offices/com/speeches/99-14.htm. Upon his death in 1999, Acting Commissioner of Patents and Trademarks, Q. Todd Dickinson, called Judge Rich "the single most important figure in twentieth

over his inventions needs to satisfy three basic requirements.[85] Article 101 of the USC 35 gives and overview what is patentable and from which all other patentability requirements derive from. Further same article stipulates that anyone who invents or discovers a process, machine or compositions of matter that is in any way new to the science or that or it's a new and useful improvement of it , has a right to request a patent a patent grant.[86] Going from that if the patentee files a claim for an invention is in a way useful more exactly that it has an utility, that is new and that the process for coming up of invention or if the invention itself is a process is not obvious. More on the each patentability requirement will be addressed in the later subchapter. The patentee needs to file hers patent claim to United states Patent and Trademark office (USPTO), which is a s an agency of the U.S. Department of Commerce. As it could be concluded from the name of the office, its primary role is to confer the patent for protection of inventions and to register trademarks. Regarding the patent granting function USPTO examines patent applications and only grants patents on inventions when applicants dully satisfy the patentability requirements. It provides services such as, recording of previously granted patents, maintains search files of U.S. and foreign patents, etc. . Importantly to note patent granted by the USPTO is U.S. patent grants are effective only within the United States, on its territories, and. possessions. . The patent claim at the USPTO may be filled for three different type of patent claims. Those are principally claims for Utility patents, Design patents, and Plant patents. Utility patents is patent that is grant for the manufacture, machine process compositions of mater type that are of course new and useful too.

century intellectual property law," and noted that "[h]is life's work will illuminate the American patent system for decades to come."; Title 35 concerns the establishment of the United States Patent and Trademark Office, the requirements for patentability, the grant of patents, and the protection of patent rights. 35 U.S.C. §§ 1-318 (2000).; See In re Bergy, 596 F.2d 952, 960 (C.C.P.A. 1979), vacated sub nom. Diamond v. Chakrabarty, 444 U.S. 1028 (1980), affd sub nom. Diamond v. Chakrabarty, 447 U.S. 303 (1980).; See Donald L. Zuhn, Jr., DNA Patentability: 'Shuting the Door to the Utility Requirement;, 34 J. Marshall L. Rev. 973 (2001).

[85] Donald L. Zuhn, Jr., DNA Patentability: Shuting the Door to the Utility Requirement, 34 J. Marshall L. Rev. 973 (2001).

[86] U.S.C 35, Art 101.

Of inventions new and useful. Also this patent maybe awarded for the invention claim that represent an new and useful improvement of a manufacture, process or a composition of a matter. Design patents is granted for inventions where the patentee wants to protect the physical appearance of an object, however with the requirement that the specific appearance cannot be divided from the object. A plant patent can be obtained to protect new and unique plants however; the specific requirements for this type of patent differ from the previously mentioned two.

Chapter 4. EPO, USPTO Patentability requirements and characteristics of EST

This chapter will analyze each patentability requirement that are required to be satisfied while filling a patent application at EPO and USPTO. Assessment of each patentability requirement will start by explaining their legal aim and purpose and then comparing it to the EST. As it was mentioned in previous chapter aim of this chapter is to mainly confirm the research findings that EPO and USPTO concluded in theirs joint program. Every subsequent subchapter will end with the in chapter conclusion.

4.1 Invention and patentable subject matter

Interestingly EPC does not define what is exactly considered to be an invention, but in the Art. 52(2) there is a non-exhaustive list for what cannot constitute an invention *per se*[87]. This list is contained of discoveries, scientific theories and mathematical methods, aesthetic creations, schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers and presentations of information.[88] The main idea why discoveries are not able to be patentable subject matter, is due to their lack of technical effect, as it is said commonly discoveries are 'sitting there under the sun' waiting to be found[89]. This situation can only take a different course only if discovery is given a practical use then it may become patentable if it satisfies other requirements as well. Moreover if it can be proven that a discovery is more than a randomized influence of the nature that some practical use can be added then the discovery may be patentable[90]. This aspect of patenting can be troublesome for genetic inventions, due to the fact that most of them constitute a discovery. If we compare Genetic inventions to mechanical inventions, then we can conclude that the former are first discovered eventgoer their purposes is still not known. Afterwards for which sake an additional research is needed for a practical effect to be authenticated. Mechanical inventions are most of the time a practical- technical solution to a certain posed problem, the problem already known and mechanical inventions are used as a solution to that problem. In order to explain more precisely, an example will be provided For

[87] European Patent Convention 2000 Article. 52 (2).
[88] European Patent Convention 2000 Article 52 (2).
[89] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980); John M. Conley, 'Gene Patents and the Product of Nature Doctrine', 84 Chi.-Kent. L. Rev. 109 (2009).
[90] Catherine Seville, 'EU Intellectual property law and policy' 2009. Edward Elgard Publishing 98-99.; European Patent Convention Article 2000 52 (2); European Patent Convention 2000 Art 52 (1).

example a newly discovered human gene cannot be patented because it can be found in a human body already, however if for that gene a certain use can be established, a use of gene therapy then that particular gene can be patented .However it is very unlikely that for a sake of enhancing a certain gene therapy or for a need for a protein that scientist will start to look deeper into the DNA in orther to find a gene that will solve their problem.

Another important aspect which is setting a difference bar between what can be constituted as invention and what is a mere discovery is the aspect of human intervention. What is meant is that when a human gene is discovered in DNA of human or any other organism and isolated by a technical mean then it can be patentable. This situation can be seen in the *Relaxin case*. In this case patented application was held for a hormone which practical application is to relax uterus during childbirth.[91] Despite that this hormone can be found naturally inside of a human body, for further development it need to be extracted and it was by a technical mean. EPO has granted a patent for this invention. This case underlines the importance of the 'isolation by technical mean'. If a substance that is found in nature in order to be further exploited needs to be extracted by human intervention, in that case it is patentable. Whatsoever if the newly extracted substance is new in a sense that in that form of existence didn't occur in nature before then the substance is patentable.[92] As a further establishment that genetic inventions are considered to be a patentable subject matter the can be seen in EPC 2000 Rule 27. In that Rule it is stipulated that if a biological material which

[91] *Howard Florey/Relaxin*, T74/91 [1995] EPOR 541. Now confirmed by EPC 2000, Rule 27 (a). See Also Biotech Directive Art 3 (2). See, Catherine Seville, 'EU Intellectual property law and policy' [2009]. Edward Elgard Publishing

[92] Catherine Seville, 'EU Intellectual property law and policy' 2009. Edward Elgard Publishing.

human gene certainly is, by use of technical process is isolated from its natural environment where it occurs is going to be patent eligible.[93]

What can been patentable in United States is regulated by U.S.C 35 in section 101 where it is expressed that anyone who invents or discovers a composition of matter, machine or a process which is new and useful will be granted a patent.[94] Although section 101 mentions both the words invention and discovery it does not provide for the clear distinction between the former and latter. The famous case in the United States where the bar was set for the distinction between invention and discovery is the *Diamond v. Chakrabarty*, case.[95]

Going further ahead in the above-mentioned provision it could be understood that section 101 infers that for an invention to be granted a patent it must not be a discovery, it must be new or novel and it must be useful which implies that it needs to have an established utility. Requirement of utility and novelty well be explained in later chapters. However the requirement that the patent claim is not a discovery is very similar with the European patent law and same principles play the role of understanding that notion. The other famous case in the United States where the example are gene related invention's is the *Myraid Case*. Patent claims for this case were BRCA1 and BRCA2 genes and specific mutations that can help to indicate does a woman has a risk for developing the breast cancer[96]. Here the Supreme Court contested that naturally occurring genes and genes sequences, and their natural derivative products, cannot be patentable however, the Court also held that if the gene is crated or better say isolated in the laboratory synthetically it is

[93] EPC 2000 rule 27 (a). See Li Westerlund, Gerry Kamstra in. Hacon/Pagenberg 'Concise European Patent Law, Second Edition' [2008] Kluwer Law International.
[94] 35 USC Chapter 10, 101.
[95] Diamond v. Chakrabarty, 447 US 308-309 (1980).
[96] *Association for Molecular Pathology v. Myriad Genetics* [2013] 569 U. S. ____ (2013).

patentable due to the reason that isolation changes the genes molecular structure and thus is different from the one found in the nature.[97] By Comparing the requirements of the patentable subject matter in Europe and United States the following could be concluded. The two main point conceding the patentability of human gene patents as subject matter is that do not only represent a discovery without a practical and the isolation requirement. The issue if a genetic invention is just a discovery could be a difficult threshold to go over. Form the above mentioned explanations of what is EST and what are its established and possible practical uses, the problem that they are inventions which industrial applicability or utility environment is unknown due to the fact that they used to locate gene which function is unknown at the moment of localization. If there is no exactly established industrial applicability in Europe and utility in United States, EST as patent claims will hardly satisfy those requirements, more on this problem will be said in the industrial applicability/utility chapter.

Considering the issue that compounds that could be already to be existing in nature, the conclusion is that EST could satisfy this requirement. EST are a product of sequencing cDNA, a clone of the DNA but with one difference without the non-protein coding regions introns. cDNA can only be made by a technical process and EST "being short sub-sequence of a cDNA sequence"[98] is derived by technological mean as well. Moreover the way EST are put together, their structure as such cannot be find in nature.[99]

[97] Ibid.
[98] See From Wikipedia, the free encyclopedia, 'Expressed sequence tag'
[99] Case T 0272/95, *Relaxin/Howard Florey Institute* , 23 October [2002]

4.2 Novelty

As mentioned before novelty is one of the fundamental patentability requirement. In the EPC 2000 it is regulated in the Article 54 (1) where it expresses that "An invention shall be considered to be new if it does not form part of the state of the art"[100]. The legislators reason behind this wording in article 54 (1) could probably be accredited to their desire not to allow the state of the art be re patented.[101] With that said the invention can only be considered novel if it satisfies one more requirement and that's not to be part of the state of the art in any way. State of the Art can be defined as all information that were made available to public in any way, before the European patents application filling date.[102] The wording 'in any way' is understood to be means of public disclosure by written and oral explanation or by usage.[103] Written description generally refers to documents but also written description can be made by drawings of an invention as well[104]. Regarding the oral disclosure there is no difference if the oral disclosure is made by one or more individuals.[105] Finally the disclosure by use can be distinguished to use of a product invention which can be done buy only exhibiting the product invention and disclosure by use regarding process inventions for which a genuine use was performed.[106] Also the state of the art is made of information's that were disclosed by any means anywhere in the world, which implies

[100] European Patent Convention Article 54 (1).
[101] See, *Allied/Friction reducing additive*, G2 [1990-85] EPOR 73, 88.; Catherine Seville, 'EU Intellectual property law and policy' 2009. Edward Elgard Publishing.
[102] European Patent Convention Article 54 (2).
[103] Ibid.
[104] Johnson in. Hacon/Pagenberg 'Concise European Patent Law, Second Edition' [2008] Kluwer Law International 38-48.
[105] Ibid.
[106] Ibid.

that information disclosed on the territory of the EPC 2000 non signatory is counted into the state of the art as well.[107] Disclosure by alleged means puts the 'new' invention in the basket of state of the art which will amount to denial of a patent. Fact that additionally complicates the novelty requirement is that the public is not actually needed to see or to be present at the moment of the disclosure. [108] Vis-à-vis accessing the novelty requirement at EPO proceedings, the crucial fact to decide on is the filled invention application, more precisely its technical characters new to a person skilled in the art. EPC 2000 does not provides with the definition of the person skilled in art, however EPO examination guidelines are providing who should be considered as a person skilled in art. For The person that is skilled in the art should be supposed to be a skilled professional in the relevant field of technology and who only has regular knowledge and skill and is aware of what was common general knowledge in the art at the relevant date is.[109] The lack of novelty can be constituted in two way in connection with the person skilled in art. The explicit and implicit manner.[110]

United States as well recognize the novelty requirement. The notion that the invention need s to be new in order to be patented furthers is emphasized in 102 U.S.C.[111]. The novelty requirement has its legal justifications. "As patent lawyer say an invention that is anticipated from the prior art is a discovery that already exists in storehouse of knowledge"[112]. People who work in a specific field can or know it, can use it, and can bring it to public intention In the United States, an invention

[107] Catherine Seville, 'EU Intellectual property law and policy' 2009. Edward Elgard Publishing, 100-104.
[108] Ibid.
[109] European Patent Office Examination Guidelines, Part G 'Patentability', Chapter VII- 'Inventive Step' 3.Person Skilled in Art. [2017].
[110] Melanie J. Howlett Andrew F. Christie, 'An analysis of the approach of the European, Japanese and United States Patent Offices', IIC 2003, 34(6), 581-602.
[111] U.S.C 35 103.
[112] Rochelle Cooper Dreyfuss, Roberta Rosenthal Kwall, 'Intellectual Property, Trademark, Copyright and Patent Law' Second Edition, Foundation Press New York, New York 2004.

is not considered to be novel if it is priory use or known in the United States.[113]As well if the panted has already been granted in the United States or disclosed and publish and patented in any foreign country.[114] Unfortunately, the notion of novelty is not described in further detail by the USPTO in its Guidelines. However certain theories such as anticipation theory aids in understanding the novelty concept in the United States patent system. Anticipation theory essentially a checking test of the novelty requirement, the test is applied in a manner that if an inventor by filling his patent claim is infringing an invention, if yes by default the invention is not novel[115]. In conclusion with the novelty requirement the Trilateral Offices had found that all of their six hypothetical claims were satisfying the novelty requirement eventgoer there were no supplementary explanation for justifying that assertion.[116] "Presumably the requirement of novelty is not an issue because each of the cases had no prior art with high similarity to the claimed sequence."[117] It could be agreed with this because starting from the fact that genetic material and EST as such is considered to be a chemical compound[118]. Is eligible for application chemical novelty rule, which states that a chemical will not destroy the novelty of another chemical.[119] EST as technically isolated compound of the cDNA is different on the molecular level from the full length DNA sequence, as to the reasons of their different coding/noncoding genes presence. Due

[113] 10 U.S.C. 102.; Melanie J. Howlett Andrew F. Christie, 'An analysis of the approach of the European, Japanese and United States Patent Offices', IIC 2003, 34(6), 581-602.
[114] Ibid.
[115] Gene Quinn, 'Patentability: The Novelty Requirement of 35 U.S.C. 102' [June 10 2017] http://www.ipwatchdog.com/2017/06/10/patentability-novelty-requirement-102/id=84321/ Accessed 04.04.2018 .
[116] Melanie J. Howlett Andrew F. Christie, 'An analysis of the approach of the European, Japanese and United States Patent Offices', IIC 2003, 34(6), 581-602.
[117] Ibid.
[118] Stempel, Jonathan. "Myriad Wins Gene Patent Ruling from US Appeals Court."Reuters. Thomson Reuters, . http://www.reuters.com/article/2012/08/16/us-myriad-patent-idUSBRE87F12K20120816 Accesed 04.04.2018.; Gabriel Ben-Dor, 'Ethics of Gene Patenting: Moral, Legal, and Practical Perspectives', [2012], Stanford-Brown iGEM, Accessed 04.04. 2018. http://2012.igem.org/wiki/images/d/dc/Gene_Ethics.pdf .
[119] Leslie G. Restaino, S teven E . Halper n and Dr. Eric L. Tang, 'Patenting DNA-Related Inventions in the European Union, United States and Japan: A Trilateral Approach or a Study in Contrast?', http://www.lawtechjournal.com/home/Articles/2003/02_030617_halpern.pdf , Accessed 06.04.2018.

to their different structure an EST is could be regarded as novel to the full length DNA sequence. Arguments stated above in the patentable subject matter subchapter may be used was well in establishing would the EST satisfy the patentability requirement of being novel.

4.3 Inventive step and non-obviousness

Inventive step as one of the possibly most difficult requirements to satisfy in the applied invention is a genetic invention. This requirement is only going to be assess if the former requirement of novelty is satisfied. Starting from the Europeans patent requirements of inventive step is specified in in article 56 of EPC 2000. By the mentioned article the requirement is defined in following way "An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art."[120]Looking at the provisions, it is obvious that it is made up of three different part which in order for an invention to have an inventive step, needs to be fulfilled cumulatively. In the first section of the article 56 EPC 'in regard to state of the art' is possibly meant that the invention while being compared with the state of the art is different which means that is novel.[121] This further proves the alleged connection between novelty and the inventive step. The way what comprises the state of the art is same as with the novelty with only two difference, national or earlier European patents are not counted in and the so called "mosaic" method where the prior art information is gathered from different areas.[122] Second requirement is that invention is not obvious. In spite of this explicit stipulation of

[120] EPC 2000 Article 56;See Catherine Seville, 'EU Intellectual property law and policy' [2009]. Edward Elgard Publishing.
[121] Johnson in. Hacon/Pagenberg 'Concise European Patent Law, Second Edition' [2008] Kluwer Law International.57-62.
[122] European Patent Convention 2000 Art 56.

the EPC 2000 that for invention to have an inventive step it must not be obvious, there are no further explanation on what is meant by the term not obvious or what is threshold in that manner. Nevertheless the EPO Guidelines are providing some explanation. The invention is considered to be obvious if it is on the same technological level as the prior art. It is not contested what type of difference of levels of the invention and the state pf the art it should be, but by logical conclusion it is hardly imaginable that EPO would grant a patent over an invention that is lees advanced than the state of the art.[123] It is a bigger probability that the goal Of the EPO is to award a patent to an invention that represent a technological leap over the state of the art. [124] Whether is the invention obvious or not is the question that should be on the priority date or before the filling date to a person skilled in the art.[125] If invention claim contains some non-technical aspect beside the technical ones only the latter's ones are taken into account while assessing the inventive step. In the previous chapter the notion of 'person skilled in the art' was explained. But also the person skilled in art is not necessarily an individual. Sometimes an individual skilled in the art is going to be skilled only in one area of the art.[126]For that reasons maybe she will need an assistance from other areas of science.[127]The general policy of the EPO's examination of inventive step in an application is famously called 'The problem solution approach'[128]. This approach has been used by the EPO for more than 25 years.[129]The legal basis for consisting this type of approach undergoes

[123] European Patent Office, Examination Guidelines, Part G, Chapter VII, 'Obviousness', https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_4.html , Accessed, 05.04.2018.
[124] Catherine Seville, 'EU Intellectual property law and policy' 2009. Edward Elgard Publishing.
[125] European Patent Office, Examination Guidelines, Part G, Chapter VII, 'Obviousness', https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_4.htm , Accessed, 05.04.2018.
[126] Johnson in. Hacon/Pagenberg 'Concise European Patent Law, Second Edition' [2008] Kluwer Law International, 57-60.
[127] Ibid.
[128] European Patents Office 'Guidelines for Examination' accesed https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_5.htm .
[129] Johnson in. Hacon/Pagenberg 'Concise European Patent Law, Second Edition' [2008] Kluwer Law International, 59-60.

from the article 42 (1) (c)[130]. The article states that description of the invention should explain the invention, as it was claimed, in a manner that eventgoer that the exact technical problem is not explained it and solution to it should be easily understood.[131] As well any beneficial effect should be disclosed with a reference of the prior art.[132]When the description of an invention is disclosed in this way then the problem to a solution approach can be applied. The EPO Examiner Problem to solution approach applies in several sub steps. Namely those steps are identification of the technical field of the invention, identification of a prior art which will later be compared with the invention then the technical problem which invention is solving and finally the test in which whether going from all technical claims or just from the claimed solution is obvious to the skilled person from the relative filed of expertise.[133]. As it was mentioned before in the novelty chapter skilled person in the art is a person that only possesses general knowledge regarding the relevant field. However certain things must be lacking and that is the capability to invent[134]. Additionally person skilled in the art should be of a cautious nature nor should be willing to explore uncertainties in the relevant field or to take risks by doing that.[135]The central point in the problem to solution approach is whether the invention is obvious to the skilled person in the field or not. Moreover would the skilled person solve the technical problem with the help of prior art teaching come up with the same inventive idea or not. Also by using would/could methodology it is stressed that could the skilled person in the field come up with the specific inventive step is not of importance rather if she would. With finding that the person skilled in art would arrive with the same

[130] Ibid.
[131] European Patent Convention Article 42 (c).
[132] European Patent Convention Rule 42.; Johnson in. Hacon/Pagenberg 'Concise European Patent Law, Second Edition' [2008] Kluwer Law International 38-47.
[133] Catherine Seville, 'EU Intellectual property law and policy' 2009. Edward Elgard Publishing,104-107.; See *Comwik/Two* Identities T641/00 [1979-85] B EPOR 362, 365.
[134] Ibid.
[135] Ibid.

conclusion on how to solve a technical problem in the same manner as inventor did in that case the invention would fail the inventive step test at the EPO examination proceeding.[136]

In North Amerika the patentability requirement of inventive step is knows as non-obviousness requirement. Article 103 of U.S.C is where the requirements is explained which an invention needs to satisfy in order to be non-obvious.[137] The supposed aim of the 'non obviousness', is to reward the claim which is not merely a progress happening in the normal course of event, but constitutes an act resulting out of the intellect of the inventor[138]. Furthermore there is a one sub requirement that invention needs to satisfy first. That is that invention must be described according to section 102 requirements.[139] Very similarly with the EPO's problem to solutions problem technique article 103 stipulates that when an invention is almost the same as the prior art and that whole invention is obvious to the person skilled in the art at the moment when it was made is considered to be obvious.[140] Also, article 103(a) states that "patentability shall not be negative by the manner in which the invention was made."[141] This explains the aim of the stipulated article, which is that contribution to the general knowledge in certain area gets the advantage over the means how that knowledge is obtained.[142]. Because the scientific knowledge in an area advances rapidly it sets a threshold that the invention needs to satisfy in order to be non-obvious goes further up.[143] Anyway the substantive part of the non-obvious requirement is very similarly composed as the counterpart

[136] Ibid.; Melanie J. Howlett Andrew F. Christie, ''An analysis of the approach of the European, Japanese and United States Patent Offices', IIC 2003, 34(6), 581-602.
[137] U.S.C 35 Art 103.
[138] Ashish Pareek, Shivendra Sing 'Concept of Obviousness: Scenario post KSR International v Teleflex Inc', NALSAR University of Law, 3-4-761, Barkatpura, Hyderabad 500 027, Journal of Intellectual Property Rights Vol 13, January 2008, pp 7-18.
[139] Ibid.
[140] Ibid.
[141] Ibid.
[142] M. Scott McBride, Patentability of Human Genes: Our Patent System Can Address the Issues Without Modification, 85 Marq. L. Rev. 511 (2001).
[143] Rebecca S. Eisenberg, Patenting the Human Genome, 39 Emory L. J. 721 (1990)

of inventive step. For example prior art, the mosaic way of acquiring prior art, notion of skilled person etc.[144]As well there is an application of a test when assessing non-obviousness of the invention. However in United States this test is established by the case law and not by the patent office like Europe. The decision of the Graham v. John Deere Co from 1996 has established the Graham test.[145] This test is comprised of several requirements as the 'problem to solution'. Those requirements are the following: scope and content of the prior art needs to be determined, differences between the prior art and the claims, what is the level of ordinary skill in the prior art and secondary considerations of non-obviousness.[146] The latter represent a bundle requirements that are also recognized as objective evidence of 'non-obviousness'[147]. Those 'objective evidence of non-obviousness' are common sense, effects of the market ,unsolved needs, failure of others etc.,[148] for example the invention will not be rendered as obvious if the invention process was obvious to try.[149]After some while another test in a way updated the Graham requirements, the so called 'Synergism test'. The 'Synergism test' differs from graham in the connotation that it gave a bigger aspect to the to the inventions ability to produce something.[150]However this idea was abolished in 1979. Afterwards a new rule emerged. This rule is known as TSM 'test'. This rule

[144] Song Huang,The Nonobviousness Requirement for Biotechnological Inventions - Resolving Uncertainty in Favor of Innovation, 21 Santa Clara High Tech. L.J. 597 (2004).
[145] Graham v. John Deere Co., 383 U.S. 1 (1966).
[146] Graham v. John Deere Co., 383 U.S. 1 (1966).; Song Huang,The Nonobviousness Requirement for Biotechnological Inventions - Resolving Uncertainty in Favor of Innovation, 21 Santa Clara High Tech. L.J. 597 (2004).
[147] Song Huang,The Nonobviousness Requirement for Biotechnological Inventions - Resolving Uncertainty in Favor of Innovation, 21 Santa Clara High Tech. L.J. 597 (2004).
[148] Ashish Pareek, Shivendra Sing 'Concept of Obviousness: Scenario post KSR International v Teleflex Inc', NALSAR University of Law, 3-4-761, Barkatpura, Hyderabad 500 027, Journal of Intellectual Property Rights Vol 13, January 2008, pp 7-18.
[149] See, e.g., Merck & Co. v. Biocraft Labs., Inc., 874 F.2d 804, 807 (Fed. Cir. 1989); In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988); Song Huang,The Nonobviousness Requirement for Biotechnological Inventions - Resolving Uncertainty in Favor of Innovation, 21 Santa Clara High Tech. L.J. 597 (2004).
[150] Ashish Pareek, Shivendra Sing 'Concept of Obviousness: Scenario post KSR International v Teleflex Inc', NALSAR University of Law, 3-4-761, Barkatpura, Hyderabad 500 027, Journal of Intellectual Property Rights Vol 13, January 2008, pp 7-18.

postulates that in order to find for an invitation that is obvious a prior art combined of teachings, suggestion and other motivations that will combine the information in such way that they will result to the invention[151].

Regarding the requirement of inventive step and non-obviousness EPO and USPTO come up with a very distinct conclusions. In EPO's research there was an application of the reasoning from the *AgrEvo* case[152]. The main idea in the *AgrEvo* case was that if all of the know chemical compound can be used for solving of a technical problem, then their random mixture is not going to constitute the inventive step or the problem of alternative chemicals..[153] EPO office in the Trilateral research explains when the same reasoning was applied to the EST it was concluded that the arbitrary usage of a DNA sequence to get the EST and used them as probe is not an inventive step because applying the gene sequencing technology on the cDNA will always produce EST. The only way by the EPO an EST claim can have an inventive step is when it is used for when they are used to diagnose a disease[154]. This is something that could be agreed on. If we start from the point that that the inventive step can be satisfied only if the problem to solution can be satisfied, moreover that the inventive step needs to be sufficiently different from all the state of the art only constitutes that EST claim for reasons for reasons how the ESTs are manufactured. Building up on prior knowledge is not needed in order for a person to manufacture EST by technical means. In connection to that using EST as probes cannot satisfy the problem to solution requirement due to the reason that the way how EST solve a technical problem, which is a location of a gene expressing DNA lines is obvious from the standpoint of a skilled person with the present

[151] Ibid.
[152] Melanie J. Howlett Andrew F. Christie, ''An analysis of the approach of the European, Japanese and United States Patent Offices', IIC 2003, 34(6), 581-602.
[153] Ibid.
[154] Ibid.

knowledge of a certain field. The USPTO on the contrary dealt with the non-obviousness of the EST very easily stating that due to the fact that there is no prior art for the EST they are non-obvious. This was further explained and stated when the prior art is missing then the invention does not have to what to be compared with[155]. The same conclusion could be asserted.

4.4 Industrial applicability and utility.

In the EPC 2000 the requirement of industrial application is "susceptible of industrial application when it can be made or used in any kind of industry, including agriculture."[156] The main aim that governs this requirement is that successfulness of a certain patent system can only be compared to how much its patents are being useful for the society.[157] As it can be seen the

[155] Ibid.
[156] European Patent Convention 2000 Article 57.
[157] See Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', 2017, Edward Elgar Publishing 47-53.; Micheal R Taylor and Jerry Cayford. ' The U>S Patent System and Developing Country Acesss to

article itself is implicitly divided into the three parts. The notion of 'susceptible', and the fact that the invention can be 'made' or 'used in any kind of industry. Coming from that understanding for a patent to satisfy the industrial application requirement it must disclose how the society can use and make the technology of an underlying patent as what is the purpose of that technology.[158]If the industrial application in contrary would not require for a patent to show how its technology can be made or be used and for what purpose then there would be a great chance that patents without a direct use for society could overflow the market.[159] Nevertheless less it's seemingly clear provision in the article 57 of the EPC 2000 this patentability requirement possess certain problems especially to the inventions coming from the field of biotechnology. Comparing with the novelty and inventive step requirement unfortunately EPO does not have a certain test that it can apply while assessing does a particular invention satisfy the requirement of industrial application. Also in regards with the requirement of industrial applicability it can be seen that its application be more or less strict. By applying the stricter policy for industrial application, patents that that are covering only theoretical or knowledge based technology would hardly satisfy the industrial applicability requirement.[160]Also applying this policy it can be used to set a very high threshold for patenting of any invention for which the practical use is still not established. [161]Interestingly the industrial application can also be viewed as a timing tool which purpose is to determine when a certain

Biotechnology : Does the Balance Need Adjusting ? [2002] Resources for the Future 2; Dan L Burk and Mark A Lemley,'Policy Levers in Patent Law' [2003] 89 Virginia Law Review, 1575; F Scoot Kieff, ' On the Economics of Patent Law and Policy' in Toshiko Takenaka (ed),Patenta Law and Theory (Edward Elgar 2008); Robert P Merges, Justifying Intellectual property (Harward University Press 2011) 94.

[158] See Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', 2017, Edward Elgar Publishing; 47-50.

[159] Ibid.

[160] Ibid.

[161] See Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', [2017], Edward Elgar Publishing 50-60; Stephen B Maebius, 'Novel DNA Sequence and the Utility Requirment : The Human Genome Initiative' [1992] 74 JPTOS 651.

invention ready to be patented and when further research is still needed.[162] Also the industrial applicability requirement does not allows for granting of patents to the invention which may advance the industry to certain degree but not sufficiently.[163]

As it was mention before the Article 57 of the EPC 200 may be divided more precisely its wordings may be divided into three parts which need to be assessed separately. A part of the mentioned article which sets the more general notion of the industrial application requirement EPO guidelines, Rule 42 (1) (f) and case law further aid in the interpretation of the article 57.

Consulting the EPO guidelines on the industrial application matter, the synonym for the word susceptible is capable[164]which indicates that in order for invention to be susceptible for industrial application it needs to prove its potential or future use.[165] As it is stated by reasoning in the Chiron Case, inventions satisfy the industrial application requirement when by successfully proving their use.[166] Which said in other words means that an invention needs to prove its practical use claim. Despite that said in situation where the practical use claim is very broad, patent claim is rarely passing the barrier of industrial applicability requirement. This amount to the conclusion that inventions with a general practical use are not acceptable.[167] Also like it can be seen from the *Max Plack* and *Zymogenetcis* case where the speculative claims for which is uncertain that they can be proven are not acceptable for the industrial application requirement.[168] The practical use of an

[162] See Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', [2017], Edward Elgar Publishing; 50-61.
[163] See Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', [2017], Edward Elgar Publishing 107-110.; Trevor Cook, 'Pharmaceuticals, Biotechnology and the Law' (2nd, Lexis Nexis 2009) 150.
[164] http://www.thesaurus.com/browse/susceptible .
[165] See Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', [2017], Edward Elgar Publishing; 107-113.
[166] Chiron Corporation v. Murex diagnostics Ltd [1996] RPC 535.
[167] See Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', 2017, Edward Elgar Publishing.
[168] BDP1 Phosphatase/Max Planck (T 0870/04) [2005] (EPO (TBA)) point 2.

invention should not be purely of theoretical nature, nor shall require from the skilled person in the art to further research and develop the invention so it could be used.[169] Regarding the being 'made or used' part of the article 57 it should not be understood as an alternatives between uses or made but, what's more article 57 is requiring that both made and used are fulfilled together. Going from that point that 'use' must be more than any type of mental or theoretical use and the notion 'made' amounts that does not literally means that by just capability of an invention to be manufactured in a specific industry will by itself satisfy the industrial applicability requirement. The manufactured invention needs to have a practical purpose which will provide with some sort of a result.[170] Also being 'made or use' applies as well to the invention which result, more precisely their purpose is not commercial exploitable. By traditional understanding if an invention is commercially exploitable that there is a certain market value of it is consider to be practical.[171] The third part of the article 57 of the EPC where it is stated in 'any kind of industry including agriculture', EPO guidelines are further interpretation this provision. The guidelines note that "Industry" should be understood in the broadest sense possible for example any physical activity that is technical an activity which belongs to the useful or practical sciences which are distinct from the aesthetic arts. Also it does not explicitly imply that it only considers machines or manufacturing.[172] In the United States the notion of industrial application is expresses as the utility requirement. As a reminder Section 101 of the Patent Act expresses that only new and useful

[169] See Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', 2017, Edward Elgar Publishing; Haematopic cytikine receptor/ZYMOGENETICS (t 0898/05) [2006], (EPO(TBA)) point 6.
[170] WIPO Standing Commite on the LAW of the Patents,' Industrial Applicability' and 'Utility' Requirements: Commonalities and Differences (n 58) 8. See See Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', 2017, Edward Elgar Publishing.
[171] Joshua C Benson, 'Resusciating the Patent utility Requirment, Again : A Return to Brenner v. Manson' [2000] 36 UC Davis Law Review 267. See Marta Diaz Pozo, 'Patenting Genes, The Requirement of Industrial Application', [2017], Edward Elgar Publishing 50-63.
[172] European Patent Office Guidelines, Part G – Patentability, Chapter III – Industrial application, https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_iii.htm , accessed 06.04.2018.

invention can be protected by the patent.[173] Also in the United States the origin of the utility requirement can be seen in the United States, Constitution Article 1, Section 8, where it gives Congress the power to grant exclusive rights to inventors for the sake of promoting the progress of Science and useful Arts.[174]In order for an invention to satisfy the utility requirement in the United States it needs to demonstrate that an invention basically needs to satisfy a three step requirement. Those requirements are comprised of specific utility, substantial, credible and well established utility.[175] Specific utility can be explained as the preciseness of the claimed practical use, moreover if an invention has a specific utility then it is close related to a certain matter and its utility claim is not broad.[176] Substantial utility can be explained as an invention's practical use which can be applied in the real word.[177] As well substantial utility pin points the exact time when an invention needs to satisfy it, if the invention cannot prove the utility right away as how's it is alleged in the claim and it can only be proven in time that invention does not have the substantial utility. However examination guidelines of the USPTO gives an exemption that by substantial utility is not ought that the invention is already presently available.[178]Credible utility is in the easiest manner explained an imaginable or the one that is accepted easily. In other language

[173] U.S.C 35 101.
[174] United States Constitution Article 1 Section 8.
[175] See MPEP, supra note 5, § 2107.01 (citing Brenner v. Manson, 383 U.S. 519, 148 U.S.P.Q. 689 (1966); In re Fisher, 421 F.3d 1365, 76 U.S.P.Q.2d 1225 (Fed. Cir. 2005); In re Ziegler, 992 F.2d 1197, 26 U.S.P.Q.2d 1600 (Fed. Cir. 1993)). See also MPEP, supra note 5, § 2107.02(II) ("An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.").; See Erstling Jay Salmela, Amy M., and Woo, Justin N., "Usefulness Varies by Country: The Utility Requirement of Patent Law in the United States, Europe and Canada" (2012). Faculty Scholarship. Paper 242.
[176] See Erstling, Jay; Salmela, Amy M.; and Woo, Justin N., "Usefulness Varies by Country: The Utility Requirement of Patent Law in the United States, Europe and Canada" (2012). Faculty Scholarship. Paper 242.
[177] See In re Fisher, 421 F.3d at 1371; See Erstling, Jay; Salmela, Amy M.; and Woo, Justin N., "Usefulness Varies by Country: The Utility Requirement of Patent Law in the United States, Europe and Canada" (2012). Faculty Scholarship. Paper 242.
[178] Ibid.

credible utility has its scientific foundation it is not something for example that is in contrary to the established law of physics. Finally the well establish utility can be understood as the culmination of all above mentioned utilities. Also the well establish utility needs to be measure in the test of person skilled in the art. If the person skilled in the art y reading the inventions utility claim and is able to understand and appreciate its properties and uses then it is said that the invention has an establish utility.[179]. Regarding the EST patent application and requirement of the industrial application/utility finding were not harmonized. EPO started with the explanation with; made or use' requirement and stipulated that if the EST can be made by the technology disclosed then they would just by that satisfy the industrial applicability requirement.[180] However when referring to the 'made' what can physically be made in an industry is going to be made in that industry only if it can later be applied in it.[181] This is understandable. In more explanation going from the sole ide that contributed to acquiring EST was pushed from the need to find protein coding genes faster. However even together that locations is found information such as which gene and then which protein can be synthesis is not known, if this is alleged in the application claim for the industrial applicability then it could be interpreted as a very vague one or a speculative allegation. In connection to that EPO is very likely to decline an EST invention claim if its claim for industrial applicability is does not gives certainty for what exactly it can be used.

Results that USPTO has acquired where that EST would failed the utility test.[182] The USPTO's explanation was that when the end result of EST use which is the localization of coding areas of

[179] Nathan Machin, Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act, 87 Cal. L. Rev. 421
(1999).
[180] Melanie J. Howlett Andrew F. Christie, ''An analysis of the approach of the European, Japanese and United States Patent Offices', IIC 2003, 34(6), 581-602.
[181] Ibid.
[182] Ibid.

DNA line lacks specific utility because it is still not know at the moment of finding what is the specific utility of the found genes in the DNA protein coding area. [183] By that EST at the moment of their patent would hardly satisfy all the sub requirements of the utility. This USPTO finding can further be proven with the precedent law from the *In Re fisher case*. There the claim was exactly rejected on the grounds that EST lacked specific utility because the EST corresponding genes did not have a known function at the time.[184] The overall conclusion for the EST and likeness to satisfy industrial applicability/utility is very small due to the fact that further research is need to be done in order for the exact practical use to be established.

4.5 Disclosure requirement and enablement.

I addition to satisfying the substantive patentability regiments, an invention must satisfy one more formal requirement. In the Europe this requirement is generally known as the 'sufficient disclosure of the invention' it is governed by article 83 "the European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art"[185]. In connection with this the skilled person after the reading the inventions description be able to apply right away the invention without any further research or

[183] Ibid.
[184] In re Fisher, 421 F.3d 1365 (Fed. Cir. 2005).
[185] European Patent Convention 2000 article 84.

inventing.[186]This requirement sometimes can apply very strict.[187]However certain amount of unsuccessful attempts are allowed to happen if the area of technology from where the invention comes from is not sufficiently explored.[188] Other questions which poses itself naturally how much information is needed to be disclosed for the European patent? Exacts amount that is necessary for a disclosure to satisfy the sufficiency requirement is made on case by case basis. However generally the amount that is needed to satisfy the sufficiency is established on the whole application which includes description, drawing and not just the claims.[189] Several examples where provided in the work of Storz, Quodbach and others, for example "The description must enable the person skilled in the art to obtain the claimed product described in it"[190]. Also additional explanations and disclosures will not be able to remedy the lack of sufficiency in the first claim.[191] For example just a very simple explanation that certain invention does something or provides something would not be a sufficient disclosure, more explanation would be needed in from of experiments that directly show the claimed use of the invention.[192] Other interesting thing about the sufficient disclosure requirement is that even if regarding a very broad claim if the broad claim is disclosed in that manner that invention can be reproduced throughout the whole industry the disclosure requirement will be satisfied.[193] United States practice concerning sufficient disclosure differs to some extent. Claim following the invention should be in according to three different

[186] Catherine Seville, 'EU Intellectual property law and policy' 2009. Edward Elgard Publishing, 141-142.
[187] Ulrich Storz, Martin Quodbach Scott D. Marty , Derek E. Constantine ,Matthew Parker 'Biopatent Law: European vs. US Patent Law', [2004] Springer.
[188] Catherine Seville, 'EU Intellectual property law and policy' 2009. Edward Elgard Publishing. 141-142.
[189] Johannes Lang, James Warner, in Hacon/Pagenberg 'Concise Patent Law, Second Edition' [2008] Kluwer law International.p-100.
[190] Ulrich Storz, Martin Quodbach Scott D. Marty , Derek E. Constantine ,Matthew Parker 'Biopatent Law: European vs. US Patent Law', [2004] Springer.
[191] Ibid.
[192] Ibid.
[193] Ibid.

aspects of disclosure: definiteness, enablement and best mode. One of the most important role of a patent claim is to literally disclose by words or drawings all the information that covered in the patent and for what exactly is protection being asked.[194] Patent claim represents the four corner of wall where inside the walls information what is the invention and its attributes s reside.[195] Most important legal source for the 'definiteness' is the 112 of the U.S.C where it is expressed that the claim should contain and point out on all the aspects of the inventions subject matter. This means that everything regarding the invention should be defined and explained. Assessment of the patent claims to its definiteness is done by a test where whether or not when a person that is skilled in that particular art could understand the subject matter of the invention.[196] In a case when patent claim is striped with vagueness invention is going to be rendered as non-patentable. The issue of the definiteness is basically does the patent claim represent the subject matter of the invention in the sufficiently definite way so it is understandable to the person skilled in the art. On other hand the enablement could be said to be a very similar notion, however with a slight variation. Every patent needs to pass whether the disclosure enables the use of the invention in order to receive the patent. To be enabled basically means that the level of disclosure in the patent claim is enough for

[194] Alan L. Durham, 'Patent Law Essentials ,A Concise Guide' [2009] Praeger Publishers.

[195] Alan L. Durham, 'Patent Law Essentials ,A Concise Guide' [2009] Praeger Publishers; See S3 Inc. v. Nvidia Corp., 259 F.3d 1364, 1369 (Fed. Cir. 2001) ("The purpose of claims is not to explain the technology or how it works, but to state the legal boundaries of the patent grant.").

[196] Alan L. Durham, 'Patent Law Essentials ,A Concise Guide' [2009] Praeger Publishers.; ee Microprocessor Enhancement Corp. v. Texas Instruments Inc., 520 F.3d 1367, 1374
(Fed. Cir. 2008); Young, 492 F.3d at 1346; IPXL Holdings, L.L.C. v. Amazon.com, Inc.,
430 F.3d 1377, 1383–84 (Fed. Cir. 2005); Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d
1374, 1383 (Fed. Cir. 2005). Like enablement, discussed in Section 8.6, definiteness is
determined from the perspective of one skilled in the art at the time the patent application was filed. W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1557 (Fed. Cir. 1983). A term that can be defined only in terms of a subjective point of view—such as "aesthetically pleasing"—is indefinite. Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1350 (Fed. Cir. 2005) ("The scope of claim language cannot depend solely on the unconstrained, subjective opinion of a particular individual purportedly practicing the invention.")

the person skilled in art to use the invention without further burdens and complications.[197]The way how the enablement check works is, that the text of the patent specification is look at and determine is the claim enabling. Its meaning come from the basic notion of the patent law which stipulates that for patentee in order to be granted a patent she must full disclose hers invention to that degree of understanding that anyone skilled in art may use.[198] The best mode requirement puts an obligation to the inventor that in order to get a patent for hers invention, she needs to full disclose to the public the best mode/version of hers invention. [199] The easiest way to understand the notion 'best mode' is to compare it with another disclosure requirement for example with enablement. Both requirements need to be satisfied cumulatively in order for patent claim to pass the disclosure requirement. Enablement requirement can be also held as an inventions manual, hence the best mode can be looked at as tool for checking inventor's honesty.[200]

Research that was conducted by the trilateral office joint procedure has put the opinions of EPO and USPTO on the two different sides. EPO claimed that that EST claim can pass the sufficient disclosure requirement due to the fact that disclosure of the gene sequence is enough for a skilled practitioner to use it without undue burden[201]. The technology for obtaining the EST is not complicated for the professional skilled in the art. By reading the disclosure one skilled in the art could replicate the technology for obtaining the EST and with that she could apply EST as a probe to locate the protein coding gene. This view was not shared by the USPTO. Unites States concept

[197] John C. Todaro, 'Enablement in Biotechnology Cases After In Re Goodman' [1994], the Berkeley Electronic Press.
[198] Ibid.
[199] Bingbin Lu, 'Best Mode Disclosure for Patent Applications: An International and Comparative Perspective', [2011], Journal of Intellectual Property Rights Vol 16, September 2011, pp 409-417.
[200] Ibid.
[201] Melanie J. Howlett Andrew F. Christie, ''An analysis of the approach of the European, Japanese and United States Patent Offices', IIC 2003, 34(6), 581-602.

of utility and enablement are very closely connected. In the Trilateral joint work the USPTO alleged that due to the utility/enablement connection, something that does not have a purpose or its purpose is not known yet cannot be thought.[202]Another way that the EST could fail the enablement test is in the situation that from claims specification it can be understood that the invention can be used only after further research.[203]Here if it can be constituted that the person skilled in the art after reading the specifications can only use the invention offer further undue research. If that would be applied to the situation of the EST claim, where the claim disclosed that EST can locate a protein coding gene but that the information about the protein its biological functions, it practical use can be know only after further research is done and that further research is going to last years in that case the EST would probably fail the enablement test.

[202] Ibid.
[203] John C. Todaro, 'Enablement in Biotechnology Cases After In Re Goodman' [1994], Fordham Intellectual Property, Media and Entertainment Law Journal

Conclusion

After conducting this research and assessing the four substantive and one formal patentability requirement both on the side of Europe and United States, my findings were in the alignment with findings of the EPO and USPTO in the Trilateral research. Furthermore it could be concluded that at the present moment it would be relatively hard for the EST claim to satisfy the patentability requirements in both jurisdictions. Even so an EST patent claim has satisfied some of the patentability requirements in Europe and Unites states. : Non obviousness was asserted by the United States, Europe was more favorable for the satisfaction of the enablement requirement, and on the other hand both jurisdictions have agreed up on that EST can satisfy the patentable subject matter condition. Nevertheless In order for an EST patent claim to be granted a patent it must satisfy all the five requirements cumulatively. Therefore as an answer to the research question the probability of the EST patent claim to satisfy the patentability requirements is not very high, they still would not be able to successfully overcome the patents law so with that the fear of EST claim obtaining the patent was unfounded. Even so the potential of the EST should not be rejected in such swiftly manner. The ESTs are a modern day proof that advancement in technology with every new breakthrough is one step closer to alter the fundamental norms of intellectual property law. An attempt of patenting EST can be characterized as a bold move at least. If it was successful it could probably started a chain of events which would certainly give some parties a monopolistic position in the genetic invention market. However will EST manage to become a patented invention that will foremost depend on further development of technology and current policy of a patent office where the EST patent application is being filled.

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