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INTERNATIONAL (CROSS-BORDER) REGULATION OF BIOTECHNOLOGY PATENTABILITY

master thesis

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LIST OF ABBREVIATIONS

BRCA – Breast cancer gene

EU – European Union

EBA – Enlarged Board of Appeal

EPC – European Patent Convention

EPO – European Patent Office

CRISPR - Clustered regularly interspaced short palindromic repeats

DNA - Deoxyribonucleic acid

NGO – Non-governmental organisation

OPTN – Organ Procurement and Transplantation Network

PGE - Prostaglandin

R&D – Research and development

RNA – Ribonucleic acid

SCNT – Somatic cell nuclear transfer

TT – Transplant tourism

INTRODUCTION

The relevance of the Master Thesis. It is difficult to deny the fact that intellectual property plays a key role in promotion and development of the business worldwide. Nowadays it has become even more significant for companies to protect their intangible rights than tangible ones because the first accounts for the majority of firms' assets not only on the national but also on international scale. The balanced system of granting and exploiting exclusive rights in intellectual property (IP) enhances the economic growth and development, promotes investment and creates an auspicious atmosphere for creativity and cultural thrive. It should be also noted that intellectual property by itself neither strengthen nor inhibits the economic growth, contrary, these are laws and practices which, in fact, set different vectors for how IP will affect the development in future.

Patents are considered to be one of the oldest forms of intellectual property protection. They are named to be exclusive rights for inventions in any field of technology which stimulate innovation and business development. The main underlying idea is that granting monopoly rights under patent protection is subject to the full disclosure of a particular invention, thereby giving a huge incentive to create new technologies. Protection of new inventions in biotechnology is relevant because it is the area that develops rather rapidly but returns for investments from such activity is relatively slow. On the one hand, for pharmaceutical companies, commercial laboratories and other firms involved in such business it is of significant importance to receive back what was spent on research and development (R&D) activities; on the other hand, science and society themselves are interested in biotechnological development because it gives a lot of opportunities starting from using cheaper treatments of such diseases as cancer and its orphan types, and ending up with the creation of new technologies for growing pest stable crops.

But notwithstanding the fact that there is a great number of advantages of patenting biotechnological inventions, still there are many controversial legal issues regarding this activity. Among heated matters are the morality of patents and their ethical appearance in the modern society as well as the issue of what constitutes a biotechnological invention itself under EU and international law. The debate is based upon the ambiguous idea that biotechnological inventions promote new efforts for research, business and, thus, the economic growth on a whole, thence it is rather unreasonable to hinder them within the ethical and moral considerations. Taking these matters into account, the **main research question** may be formulated:

Whether granting patents in biotechnology should be restricted by the morality concept and how it is connected with the notion "biotechnological invention".

The **aim** of this Master thesis is to find out the *possible effective ways to strike a balance between protection of exclusive rights granted for biotechnological inventions and interests of the society based on the identification of peculiarities of the concept "patentable subject matter" in biotechnology in common and continental law jurisdictions.*

The main **objectives** of this paper are the following:

1) To identify what is the "patentable subject matter" in biotechnological inventions;
2) To define the *ethical aspect* in patenting biotechnological inventions concerning genes of living organisms (DNA sequences);
3) To analyze the issue of human cloning, its pros and cons with reference to patent law;
4) To define the ethical and moral restrictions in bioprinting.

The scientific novelty and overview of the research. This Master thesis makes an input of statements for the establishment of the legal equilibrium between the protection of exclusive rights granted for biotechnological inventions and interests of the society based on comparison of different legal jurisdictions; particularly, the evolvement of ideas for biotechnology business intellectual property rights protection as well as concepts for protection of interests of the society.

The problem which is brought up has been vastly discussed and debated by various scientists and legal experts for decades.

Christian Evensen, Thomas Hoban and Eric Woodram in "Technology and Morality: Influences on Public Attitudes Toward Biotechnology" (2000) mentioned that, "Critics have identified the moral objection to biotechnology based on the commodification of life that biotechnology, especially genetic engineering, makes possible. Such concerns constitute intrinsic objections that through the use of biotechnology we are "tampering with nature".[1]

Oliver Mills in his work "Biotechnological Inventions: Moral Restraints and Patent Law" (2004) discourses that, "[…] the question of morality in essence concerns the act of creating the technology and as such problematic within the patent system, since patent law is concerned with the protection of the technology only […] there seems to be little evidence to suggest that morality provisions in patent law are there to regulate per se".[2]

Matthew Rimmer in his work "Intellectual Property and Biotechnology" (2007) stated that, "The contemporary debate over patent law and biological inventions is not new. There has been a long-standing controversy over the grant of monopolies in respect of scientific inventions

[1] Evensen, Christian and Hoban Thomas, and Woodram Eric. "Technology and Morality: Influences on Public Attitudes Toward Biotechnology". *Knowledge, Technology & Policy*, Spring, Vol. 13 Issue 1, 2000, p. 47.
[2] Mills, Oliver. *Biotechnological inventions: moral restraints and patent law*. England: Antony Rowe Ltd, Chippenham, Wiltshire, 2004, p. 10.

and technologies. There are also a number of patent abolitionists who contend that biological inventions should not be eligible for protection as patentable subject matter".[3]

John Raidt (2014) noted that, "Since unraveling the "language of life"— the landmark celebrated at the HGP press in 2003 — mankind has continued to gain a deeper understanding of cellular function at the molecular level. As the science has moved further into the domain of human genetics, however, the issues over the patentability of discovery and invention […] have grown trickier and more controversial".[4]

It should be also mentioned that besides various scientific opinions concerning patenting of biotechnology, case law also plays the significant role, namely, in practice. Such cases as *Diamond v. Chakrabarty (1980), Mayo Collaborative Services v. Prometheus Laboratories (2012), Association for Molecular Pathology v. Myriad Genetics, Inc. (2013)* and others had a great impact on shaping the legal policy in biotechnology issues with regards to identifying a patentable subject matter by virtue of analyzing the difference between discoveries and inventions as well as the degree of moral aspect of inventions in question.

Practical significance of this Master thesis lies in the following: **for companies and inventors:** it is essential for such undertakings to identify the risks taken during the R&D stage, creating the invention itself and trading it, thus practical utility lies in establishment of legal certainty and predictability when applying legal provisions of patent law which is directly connected with the protection of their monopoly rights; **for courts**: the creation of a harmonized approach towards the concept "patentability" in biotech inventions, in particular, in ethical aspects; **for the Member States and European society**: taking into account the separability of patent law systems and non-existence of a "unified patent" throughout the European Union, to create a harmonized approach towards patent laws application and a reasonable degree of certainty for society in legality of patenting biotech inventions.

In order to achieve the aim of this Master thesis author used the following **methods**: the **comparative method** was used in order to find out the main differences in understanding what can be patentable in biotechnology as well as ethical and moral concepts and their connection with patent law in common (illustrated by the USA) and continental law jurisdictions (illustrated by the EU); the **historical method** provides a deeper insight into the nascence of biotechnology patent law in the world in general and on the regional (the EU) as well as on national levels; the **analysis method** was applied throughout the scientific paper. Its usage gave a possibility to analyze legal approaches to the "patentable subject matter" criterion, handle different cases

[3] Matthew, Rimmer. *Intellectual property and biotechnology: biological inventions*. Great Britain: MPG Books Ltd, Bodmin, Cornwall, 2008, p. 1

[4] Raidt, John. "Patents and biotechnology". *US Chamber of Commerce Foundation*. 2014. P. 25. https://www.uschamberfoundation.org/sites/default/files/article/foundation/RaidtPaper.pdf

which give a precise interpretation to this criterion, to ponder over the concept of "morality" in biotechnology and to understand the abundant legal regulation applied in diverse jurisdictions; the **synthesis method** was used in order to establish common features in legal regulations of biotechnology patent law in the USA, Australia and Belgium.

The Master Thesis is divided into 4 chapters: I – Historical Development of Protection of Biotechnological Inventions; II – Patentability of Biotechnological Inventions in the USA and the EU; III – Ethical and Moral Aspects in Biotechnological Inventions; IV – Morality and Bioprinting.

In the I chapter the author describes the historical development of protection of biotechnological inventions and shows various peculiarities which were applied at different stages of history worldwide. Also, this chapter includes a description of historical development of the notion "patentable subject matter" in different countries.

In the II chapter analyzed and described the notion of "patentability" and, in particular, "patentable subject matter" under different jurisdictions.

In the III chapter the emphasis is made upon the morality aspect in biotechnological inventions, human cloning issues, genome editing and animal-related patents.

In the IV chapter the author makes an extended analysis of bioprinting and its moral view in patenting.

Main defense statements:

1) Moral restrictions in patent law in most cases negatively influences on technological development and cause difficulties in assessing patentability of a specific technoogy;
2) Society cannot serve as an indicator for what is moral and what is not;
3) It is rather difficult to reach the balance between the interests of technological advancement and the interests of society because the first has a faster pace than the law, however, the higher degree of equilibrium can be gained by virtue of mutual endeavors made by legislators, Patents Offices, courts and NGOs.

1. HISTORICAL DEVELOPMENT OF PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

1.1. DEVELOPMENT OF BIOTECHNOLOGY WORLDWIDE

The term "biotechnology" in spite of its quite modern sound, is not new in origin. Humans have been using biology and chemistry for thousands of years for creation of food products and medicine by virtue of manipulation with various microorganisms. First attempts of working with living organisms appeared long ago when people applied cross-breeding in order to obtain new species of plants and animals. Nowadays the modern technology allowed to develop this activity to such an extent that it occupies an enormous part in such spheres as pharma – around 55%, industrial production – 41% and agriculture – 4%.[5] Inventors have been using patenting system in the described area for hundreds of years. Interestingly, the first biotech patent was obtained in 1787 in the UK under number GB 178701625 for a yeast-like composition used for baking and on 29 July 1873 a scientist Louis Pasteur patented his improved yeast-making method in French Patent Office.

Without a doubt pharmaceutical area is the most important as it ensures health and long duration of life. That is why the rapid biotechnology development is utterly crucial for obtaining new, more advanced and effective medicine. One of examples can be the patent (U.S No 1,469,994) which was obtained in October 1923 in the USA by Frederick Banting, Charles Best and James Collip for an "*Extract Obtainable from Mammalian Pancreas or from the Related Glands in Fishes, Useful in the Treatment of Diabetes Mellitus, and a method of preparing it*".[6] Before the medicine was discovered, this disease was considered as such that could not be cured and subsequently led patients to the death. But the invented extract saved a lot of peoples' lives back then and is being applied now in the treatment after several improvements of its compounds.[7]

In 1969, a German inventor claimed a patent for creating doves with red plumage. However, the German Patent Office denied the granting of the patent because it stated that such a feature cannot be repeated. This decision was upheld by the Supreme Court of Germany. Despite this fact, it has become an important event in the history of biotechnological patenting as this

[5] European Patent Office. "Biotechnology patents at the EPO". 05.07.2017. https://www.epo.org/news-issues/issues/biotechnology-patents.html

[6] Luigi, Palombi, *Gene Cartels: Biotech Patents in the Age of Free Trade*. UK: Edward Elgar Publishing Limited, Cheltenham, 2009, p. 255, https://books.google.be/books?id=3wbTS5HYqy0C&pg=PA255&dq=Extract+Obtainable+from+Mammalian+Pancreas+or+from+the+Related+Glands+in+Fishes,+Useful+in+the+Treatment+of+Diabetes+Mellitus,+and+a+method+of+preparing+it&hl=ru&sa=X&ved=0ahUKEwju7pPf6_LhAhVNaFAKHcAGDTUQ6AEIKTAA#v=onepage&q&f=false

[7] Suiter Swantz IP. "Patent History: Insulin". 09.10.2018. https://www.suiter.com/patent-history-insulin/

appeared to be the first case at the EU level.[8] In the mean time, later in 1970s, the General Federal Supreme Court ruled that the patent could be granted for the inventions which contain new microorganisms if an inventor is able to show that it is reproducible.[9]

If we come back to the origin of the term "Biotechnologie", it should be noted that firstly it can be defined as an "*Application of the principles of engineering and biological science to create new products from raw materials of biological origin, for example, vaccines or food*."[10] Before the 1970s biotechnology was more connected to intellectual creativity and scientific curiosity, only in 1980s an element of commercialization has become of a high importance and biotechnology started to grow quite rapidly. A lot of modern tools which allow DNA manipulations, growth of tissues etc are very promising both for science and business. In relation to this matter, the major breakthrough in biotechnology was a discovery of DNA in 1953 by Francis Crick and James Watson. It was definitely a great advancement in biotechnology on a whole as the secret of the whole life was discovered.[11] This technology demonstrated that "*DNA not only explains the very essence of every living cell but it promises great possibilities for future*".[12]

After the adoption of European Patent Convention (further - EPC) in 1973, the first case in the EU laid down foundations for patenting living things. It was ***Genentech-I/Polypeptide*** expression.[13] In this case the Technical Board of Appeal overturned the Decision of Examining Division and allowed the appeal. The patent concerned the human's hormone of growth which included a recombinant organism – plasmid. The main claim of the invention was based on the abilities of the plasmid which after being inserted into a bacterium, controls the expression of polypeptide. The Examining Division claimed that there was insufficient disclosure and that all embodiments of the invention "*As set out in the claim […] were capable of performance by the skilled man in a repeatable manner without practicing inventive skill*".[14] Also according to the

[8]Isguder Bora, "Biotech Patents in the World We Live In", 2017, p. 5, https://scholarship.shu.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1915&context=student_scholarship

[9] Dr. Sreenivasulu and Dr. Raju. *Biotechnology and Patent Law: Patenting Living Beings* (Delhi, India, Rashtriya Printers, 2008), p. 39.

[10] Ashish Swarup Verma, Shishir Agrahari, Shruti Rastogi. Biotechnology in the Realm of History. J Pharm Bioallied Sci. 2011 Jul-Sep; 3(3): 321–323. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3178936/

[11] Leslie A. Pray. "Discovery of DNA Structure and Function: Watson and Crick". Scitable by nature education. 2014. https://www.nature.com/scitable/topicpage/discovery-of-dna-structure-and-function-watson-397

[12] Kojo Yelpaala, "Owing the Secret of Life: Biotechnology and Property Rights Reserved", 2000, p. 11, https://pdfs.semanticscholar.org/c73c/fac5bc5ba1fbdb4f362ad8fff0d48017aab3.pdf?_ga=2.18591537.966995086.1554467227-1666294141.1554467227

[13] Dr. Sreenivasulu and Dr. Raju. *Biotechnology and Patent Law: Patenting Living Beings* (Delhi, India, Rashtriya Printers, 2008), p. 39.

[14] Oliver, Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (Routledge, New York, 2016). Isguder Bora, "Biotech Patents in the World We Live In", 2017, p. 6, https://scholarship.shu.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1915&context=student_scholarship

Division, since the claim described the invention by what it did, and "*"An invention defined by what it did, rather than what it was, could not 'define the matter' for which protection was thought*", the Division refused to grant the patent in this specific case.[15] But the Technical Board disagreed on this matter, differentiating between the *non-essential* and *essential features* of an invention.[16] The Board also stated that in case of biological process – it cannot be patented, whereas non-biological – it can. Namely, the court has ruled out that the invention must be patentable as it did not constitute a biological process and was rather a non-biological one. To my mind, the Examining Division refused to grant exclusive rights on this invention merely because the question about patenting the life form was raised. In spite of the fact that it was not made directly, still the Division could pave the way for denial through non-sufficient disclosure and inventiveness criteria. But the fact that inventors dealt with the recombinant plasmid frustrates the objection because in this case, the DNA of bacteria is not naturally-occurring and thus could be patentable.

Another case which worth attention that has influenced the historical development of biotechnology patentability was held in 1911 in the USA between ***Parke Davis & Co*** which is now a subsidiary of a well-known pharmaceutical company Pfizer, and ***H.K. Mulford Co.*** concerning the patentability of an extract from suprarenal glands[17] of living organisms. Both claimed that the granted patent should have been considered as invalid. However, the Circuit Court ruled out that if the substance was taken out of a living organism and modified for scientific aims, then such a substance can be patentable. Moreover, the Court also stated that, "*If it was merely an extracted product without change, there is no rules that such products are not patentable*"[18]. The Court of Appeals further supported the decision of the Circuit Court and commented, that the substance derived from a living organism which was extracted and purified is in principle patentable.[19] In the case ***In re Bergstrom*** 1970 it was rejected in patenting of two compounds as PGE_2 and PGE_3 because of lack of novelty element. The Board stated that, "*Failing to find pure PGE_2 and PGE_3 described in the Bergstrom publication, the board in turn seems to have premised its decision on the inherency of an impure form of PGE_2 and PGE_3 in products resulting from certain procedures that are described in that reference*".[20] Nevertheless, the Court in this case decided contrary and opinioned that as two of these elements were purified and did not exist in the nature, they could be patentable. The Board then tried to argue this

[15] Ibid. P. 6
[16] Ibid. P.6
[17] A part of endocrine system, situated on the top of kidneys.
[18] Parke-Davis & Co v H K Mulford & Co, 196 F 496 (2d Cir 1912). Ibid. P. 7
[19] Ibid. P. 7
[20] Application of Sune Bergstrom and Jan Sjovall, 427 F.2d 1394 (C.C.P.A. 1970). Justia US Law, https://law.justia.com/cases/federal/appellate-courts/F2/427/1394/268007/

comment on the ground that the form of two claimed compounds was impure: "*Appellants argue here, and below, that the board improperly used their own application as "circumstantial evidence of that fact*". *It is appellants' view that the fact of inherency was hidden from the world until they discovered it, and disclosed it in the present application*."[21] In its turn the Court stated that, "*Impure form of the compounds are the only ones to currently exist as a point of reference, then the pure forms of these compounds that are created are considered as new an novel an comparison with the previous ones*".[22] In these two cases it is noticeable that the main question which was posed for consideration is *What constitutes a purified living form*? In both situations I would rather agree with the decisions of the Court that an extracted form from a living organism, subsequently purified, should be patentable as it has nothing to do with what exists in nature except the fact that it was firstly extracted from a biological material. However, I would not accept the position that, in general, everything what is extracted from the living organism is already something that is non-existing in nature and, by virtue of this, can be patentable. Indeed, at the moment when the decision was taken, there was no explicit prohibition on patenting of what was extracted from nature. But personally for me such a broad interpretation can create a lot of disputes and mismatches in the court practice. It should be mentioned, that what really matters is that such a form should be purified, i.e. *cleaned, modified*. In latter decisions courts would come to this explanation just to emphasize that it is not really enough to patent something that was initially extracted from the living organism without further manipulations. So, why actually courts are so conscious about this? I think the answer is quite simple: if a DNA or other substance was merely extracted from nature without being purified, then it has nothing to do with novelty. The fact that a scientist just takes a living part from the whole organism – does not bring in something new and therefore cannot be even considered as an invention.

In *re Bergy* was a case which took place in 1977 in the US the Court has stated that,

> *The law unhesitatingly grants patent protection to new, useful and unobvious chemical compounds and compositions […] We see no sound reason to refuse patent protections to microorganisms themselves – a kind of tool used by chemists and chemical manufactures in much the same way as they use chemical elements, compounds and compositions which are not considered to be alive,* ***notwithstanding their capacities to react and to promote reaction to produce***

[21] Application of Sune Bergstrom and Jan Sjovall, 427 F.2d 1394 (C.C.P.A. 1970). Justia US Law, https://law.justia.com/cases/federal/appellate-courts/F2/427/1394/268007/

[22] Application of Bergstrom, 427 F2d 1394 (CCPA 1970), Cited from: "Isguder Bora, "Biotech Patents in the World We Live In", 2017, p. 8, https://scholarship.shu.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1915&context=student_scholarship"

new compounds and compositions by chemical processes in much the same way as do microorganisms.[23]

The Court also considered that there is no need to deprive a claimant or inventor from obtainment of a patent for a microorganism if it is new, useful and unobvious, so that it satisfies all the requirements of patentability other than enumerated categories.[24] So, it simply means that biologically purified microorganisms can be patented if they meet all the basic requirements set down in law. The fact that they produce the same functions as the naturally existing does not mean that they cannot be subject to IP protection.

Undoubtedly, the development of biotechnology regulation was not univocal. Not always it was considered as a positive area, notwithstanding the fact that new technologies are inalienable from human's existence. A riotous discussion regarding biotechnology and its impact on human's health began in 20th century at the time of several important documents in IP biotechnological protection sphere were adopted (e.g. TRIPS 1995, Biotechnology Directive 1998, European Patent Convention 1973). At that moment the problem was envisaged in various angles and society, in particular, the European one, did not always accept changes in biological sphere. A bright example can be made with the reference to adoption of the Convention on Biological Diversity and Cartagena Protocol on Biosafety signed in 1992 and 2000 respectively. European society simply "rejected" modified products which as the result disappeared from the markets' shelves, but, at the same time, North America had more loyal attitude towards biotechnology and particularly GMOs and thus products which contained those organisms filled in the stores for over than 5 years.[25] In 1992 during *Agenda 21* nations have recognised biotechnology as „*an emerging knowledge intensive field*"[26] which „*Is a set of enabling techniques for bringing about specific-made changes in deoxyribonucleic acid (DNA) or genetic material in plants, animals and microbial systems leading to useful products and technologies*".[27] It was also considered significant to establish an environmentally sound management of biotechnology, to endanger public trust and confidence, to promote the development of sustainable applications of biotechnology and to establish appropriate enabling mechanisms, especially within developing countries through "*[…] increasing the availability of food, feed and renewable raw materials, improving human health, enhancing protection of the environment, enhancing safety and developing international mechanisms for cooperation, establishing*

[23] "In re Bergy, 563 F2d. 1031, Federal Curcuit". Ravel, https://www.ravellaw.com/opinions/11c7ea3e21052261f5c32895b56a6a2c
[24] Ibid.
[25] Julian Kinderlerer, "Regulation of Biotechnology: needs and burdens for developing countries", accessed 2019 January 15, http://wedocs.unep.org/bitstream/handle/20.500.11822/9992/Bt%20regulationjk.pdf?sequence=1&isAllowed=y
[26] Agenda 21 (1992), preamble to Chapter 16, https://sustainabledevelopment.un.org/content/documents/Agenda21.pdf
[27] Ibid. Chapter 16

enabling mechanisms for the development and the environmentally sound application of biotechnology".[28] A relevant document which has represented a dramatic step forward in the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the use of genetic resources was the Convention on Biological Diversity adopted at the UN Conference on Environmental Development (the Rio „Earth Summit") in 1992.[29] Already then countries have agreed that there are possible risks to health of human beings because of the application of modern biotechnology but at the same there is a doubt about what are the advantages of its application.[30] This can be envisaged in art. 8(g) of the Convention as the parties should in particular, „*establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health*".[31] However art. 19(2) of the Convention points out the possible benefits of biotechnology and calls upon states to „*take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms*".[32] After lengthy discussions, the Cartagena Protocol on Biosafety was adopted as a step to draw attention to promotion of the modern biotechnology and the needed adequte level of its protection: „ *[...] the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements (art. 1 of the Protocol)*".[33]

[28] Ibid. Chapter 16
[29] Convention on Biological Diversity, History of the Convention, accessed 2019 January 15, https://www.cbd.int/history/default.shtml
[30] Julian Kinderlerer, "Regulation of Biotechnology: needs and burdens for developing countries", accessed 2019 January 15, http://wedocs.unep.org/bitstream/handle/20.500.11822/9992/Bt%20regulationjk.pdf?sequence=1&isAllowed=y
[31] Convention on Biological Diversity, History of the Convention, accessed 2019 January 15, https://www.cbd.int/convention/articles/default.shtml?a=cbd-08
[32] Ibid.
[33] "Cartagena Protocol on Biosafety". Convention on Biological Diversity. https://bch.cbd.int/protocol/text/

1.2. AUGMENTING AREA OF PATENTS IN BIOTECHNOLOGICAL FIELD

As far as it is known, patenting is a pure activity at a national level of each country. That is why, namely, patents are considered to be "territorial rights" i.e. which spread only at the particularly territory where they were obtained. But in spite of national character of these IP rights, patent law has experienced several successful attempts of harmonization. Thus, the first legal act which has become a cornerstone for future standardization and harmonization was *The Paris Convention for the Protection of Industrial Property 1883.* It has showed that patent laws which had been existing already for hundreds years could and should have been harmonized so that protection itself would be granted on a worldwide scale. Among very important provisions which can be found almost in every national patent law nowadays is the right of priority, compulsory licensing, access for an inventor to his inventions abroad etc. Also, this document is regarded to be a foothold for further convergence of international laws. The second document which is worth attention is the Agreement on Trade-related Aspects of Intellectual Property Rights 1995. As Matthew Rimmer noted, "*Patent law has become a sprawling empire, exercising dominion over a wide range of scientific fields and technologies, with few limits or boundaries*".[34] At the beginning Patent Offices granted exclusive rights concerning fungi, yeasts, viruses, moulds, algae, cell lines etc. Then the protection was broadened, first towards plants, asexually reproduced (Plant Patent Act 1930 in the USA) and then the protection was proposed for sexually reproduced plants and finally – to traditionally breed hybrid ones and genetically modified crops.[35] Animals also fell under the scope of biotechnological subject matter after polyploid oysters were recognized as patentable ones; this also made an impact on perception of patenting that future patents were subsequently granted to the Harvard oncomouse, model organisms, such as drosophila, zebra fish and even methods of cloning animals such as Dolly the Sheep.[36] But despite the fact that the ambit of the subject matter was extended quite significantly, still there are some areas prohibited to patenting: human cloning and human-animal hybridization.[37] Defenders such as lawyers, various organizations, companies made a significant input in development of protection of biotechnology, encouraging innovation and future researches in the discussed area.[38] Biotechnology Industry Organization can serve as a good example of such a defender.

[34]Matthew Rimmer, *Intellectual Property and Biotechnology (UK: Edward Elgar MPG Books Ltd, Bodmin, Cornwall, 2008), p. 3*
[35] Ibid. P. 3
[36] Ibid. P. 3
[37] Ibid. P. 3
[38] Ibid. P. 3

> *For over 200 years the carefully crafted intellectual property laws have been the driving force for innovation and progress in the USA. The U.S. patent system fosters the development of new products and discoveries, new uses for old products and employment opportunities for millions of Americans. […] Strong intellectual property protection is essential to the success, and in some instances to the survival, of over 1,200 biotechnology companies in this country. For these companies, the patent system serves to encourage development of new medicines and diagnostics for treatment and monitoring of intractable diseases and agricultural and environmental products to meet global needs*.[39]

It should be also noted that expanding of harmonization in patent law has become a lengthy and versatile activity. Passing new laws which serve as standardization for many countries is not only the one vector of work.

Obtaining patents in biotechnology is not a simple process. When we draw our attention to the amount of money which are spent on the research and development activity (R&D), clinical trials, it becomes obvious how it is costly to invent e.g. a new medicine and put it on the market. The problem is that the investment spent on this activity and the pace of returns are not equal. It is indeed hard to reach an equilibrium between finances provided and profits obtainable from inventing a new biotechnological product. In some cases a development of a new drug is known to cost approximately $800 million, while $900 million was spent at the same time to create a durable corn hybrid, and $600 million to create a different hybrid of a soybean.[40] "*The industry will not remain viable unless revenues greatly exceed the costs of drugs actually brought to market and compensate for financial risks associated with the numerous research failures that yield no marketable drugs at all*".[41] It is also said in the Directive 98/44 EC on the legal protection of biotechnological inventions that "*the field of genetic engineering research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable*".[42]

[39] Biotechnology Industry Organization, 'The importance of intellectual property', http://www.bio.org/ip/.http://www.bio.org/ip/. Matthew Rimmer, *Intellectual Property and Biotechnology (UK: Edward Elgar MPG Books Ltd, Bodmin, Cornwall, 2008), p. 3-4*

[40] Isguder Bora, "Biotech Patents in the World We Live In", 2017, p. 3, https://scholarship.shu.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1915&context=student_scholarship

[41] Ibid. P. 3

[42] Directive 98/44 EC on the legal protection of biotechnological inventions. Official Journal of the European Communities. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML

If there is no any kind of intellectual property protection it would be simple for infringers to decrease prices for copying an invention and subsequently get unauthorized profit.[43] Thus, it is obvious that in order to develop such a significant scientific area as biotechnology and, primarily, to obtain a fair revenue from R&D endeavors, companies, laboratories and other institutions aim to get an IP protection for their inventions. Without patenting this vulnerable sphere of technology would be simply not interesting to undertakings involved in bioengineering. However, there is a problem of limiting the innovation.[44] Patents are rights which are negative by nature and give their holder the full and exclusive scope of protection thus excluding all other possible undertakings to use the invention concerned. It means that even if a holder of the patent has developed a new element which can be used in other researches by other companies or laboratories, the latter cannot use it without a permission of the owner. Of course, for other market participants such a usage is not less than a „luxury" because in return for usage by virtue of licensing they have to pay fortunes to the initial developer, that's why a lot of companies do not take this risk and better create their own inventions for which they can get protection.[45]

[43] Isguder Bora, "Biotech Patents in the World We Live In", 2017, p. 3 , https://scholarship.shu.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1915&context=student_scholarship
[44] Ibid. P. 4
[45] Ibid. P. 4

2. PATENTABILITY OF BIOTECHNOLOGICAL INVENTIONS IN THE USA AND THE EU

At first sight everything looks crystal clear about patentable subject-matter issue. One can say that the invention in order to obtain protection under patent law should be new (novel), non-obvious (contain an inventive step) and be industrial applicable (contain utility feature). But in the world of such difficult field as biotechnology it is not so obvious. Thus, in this chapter I would like to address to analysis of patentability criteria for biotechnological inventions both in the United States of America and the European Union.

2.1. PATENTABILITY OF INVENTIONS IN THE USA

The U.S. has always been considered as a founder of biotechnology and patent law. It has also adopted a quite liberal attitude towards patenting of biotechnological inventions, taking into account various challenges which patent law encounters. The main legal act which constitutes the basics of American patent law – is the U.S. Constitution. Art. I Section 8 states that Congress is entitled to "*promote the Progress of Science and useful arts, by securing for limited times to […] Inventors the exclusive Right to their respective […] and Discoveries*".[46] Despite the fact that the USA Constitution gives protection to different kind of inventions, they must definitely meet statutory requirements prescribed by law.

Section 101 of the Constitution says that, "*Whoever **invents** or **discovers** any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement therefore, subject to the conditions and requirements of this title*".[47] First this power was used by the Congress in Patent Act 1970 which secured rights of inventors for 20 years.[48] This Act does not have an explicit exclusions regarding what can be patentable and what cannot. However, the United States were not always in the role of supporters to grant patents for biotechnological inventions. Before 1980 patenting such inventions was prohibited by law. The main idea which existed back then (to back up this position) was *the product of nature* doctrine. The prohibition of patenting all *physical phenomena* or *manifestations of nature* had its main point that the mere discovery of naturally occurring phenomenon is not in principle patentable because it is not an invention. In the famous ***Diamond v. Chakrabarty case 1980*** the Supreme Court grounded that "*laws of nature, physical phenomena, and abstract ideas*" are not patentable subject-matter; the reasons that "*such discoveries are "**manifestations of…nature** free to all*

[46] The Constitution of the United States, Oak Hill Publishing, ConstitutionFacts.Com, Art. 1, Sec. 8, Cl. 8, https://www.usconstitution.cc/#1
[47] 35 U.S. Code, par. 101, Legal Information Institute, Cornell Law School, https://www.law.cornell.edu/uscode/text/35/101
[48] Ibid., WIPO, https://www.wipo.int/edocs/lexdocs/laws/en/us/us176en.pdf

men and reserved exclusively to none".[49] Microorganisms which were modified could get protection only on a limited extent, such as e.g. compounds. For example, Louis Pasteur's yeast product in 1873 was granted a patent which covered a living organism. But despite that unique situation, Pasteur's patent did not become a precedent for subsequent similar cases: "*In the USA in spite of the precedent of Pasteur patent, it has become practice of the Patent Office to refuse claims to living systems as not being patentable subject-matter*".[50] I consider the case concerning patent granted to yeast-product more as an exception than as a precedent itself. Of course, in principle, even one decision can be life-changing for all subsequent similar situations but still one should not forget that Patent Offices consider each case as a unique one as well as we should take into account the historical framework. The main reason for patent approvals for living microorganisms was the society's inability to accept such rapid and for that moment flagrant idea.

In 1948 the dispute appeared between ***Funk Brothers Seed Co. and Kalo Inoculant Co.*** concerning Phizobia[51] species. In this decision the Supreme Court stated that "*an inoculant comprising a plurality of selected mutually noninhibitive strains of root-nodule bacteria is not patent eligible*".[52] The Court explicitly explained that it was a *pure discovery* and not an *invention*: "*[…] the discovery of some of the handiwork of nature*".[53] Here we deal with another quite important issue such as the division between an invention and a discovery. The difference between these two notions is quite obvious: an invention is always of a technical nature, i.e. it is a kind of a solution to a technical problem. Moreover, it should possess several features in order to be subject to patenting (novelty, inventive step and utility). All of these features are examined thoroughly by examiners also in order to establish that there is indeed an invention and not just a discovery. Surely, a discovery never has any of these features which invention possesses. Discovery is something that is proved by nature, existed in nature prior to being discovered. It means that there were no any manipulations made by man in order to obtain it. Unfortunately, not always this difference is so clear-cut. People can perceive every situation in various ways and, thus, for somebody, for example, a new microorganism will be a discovery and for somebody – a pure invention. That is why, previously, I disagreed with the too broad interpretation made in ***Parke Davis & Co*** that for something which was extracted from a living organism (e.g. a compound) can be patentable without being after manipulated by a scientist.

[49] U.S. Supreme Court Diamond v. Chakrabarty 1980, FindLaw, https://caselaw.findlaw.com/us-supreme-court/447/303.html
[50] Philip Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology*, (Oxford University Press, 4th edn., 2004), p. 224-225
[51] A soil bacterium.
[52] Funk Brothers Seed Co. v. Kalo Inoculat Co. 1948, FindLaw, https://caselaw.findlaw.com/us-supreme-court/333/127.html
[53] Ibid.

Interestingly, the 35 U.S. Constitution in Section 101 states that not only invention may obtain protection but also a discovery.[54] It is not crystal clear why legislator used two words which actually in a way contradict each other. In addition, I would like to address to a notion of *discovery* explained in Cambridge Dictionary: "*The process of finding information, a place, or an object, especially for the first time, or the thing that is found*".[55] It is obvious that the main word, synonymic to discovery is a *finding*. Literally *finding* and *invention* cannot constitute the same thing but still everybody can observe them in one legal provision. In my opinion, the logic is hidden not in literal interpretation of these words (that can be in a way unreasonable when interpreting a Constitution) but rather in a broader understanding of the word "*discovery*". In this situation a *discovery* can be understood as something new, which was not known before to the general public. In any way, it is a court's obligation to "give a life" to the legal provisions by virtue of interpretation in case hearings.

1980s became a new era of patenting in biotechnology in the USA. Radical views on patenting on live organisms were changed almost at once. The key U.S. Supreme Court decision in 1980 which set a new approach of biotechnology protection under IP law was ***Diamond v. Chakrabarty***. Previously I have stressed out on this very important case which turned the understanding of patenting living organisms upside down not only in the US but in Europe as well.

In 1972 the microbiologist Chakrabarty filed a patent application which contained 36 patent claims assigned to General Electric Co. It was a "*bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway*".[56] In simple words this genetically-engineered bacteria were capable of breaking down multiple components of crude oil. It should be also noted that this feature of not naturally occurring bacteria has become very important for treatment of oil spills. However, a patent examiner rejected claims for the alleged bacteria because 1) *microorganisms are products of nature* and 2) that *as living things they are not patentable under 35 US Constitution Section 101*. Chakrabarty appealed to the Board of Appeals of the Patent Office but the Board has affirmed the examiner's position. It concluded that Plant Patent Act 1930 in which Congress extended patent protection to some asexually reproduced plants did not cover living things such as human created microorganisms. **Defendant's position was based on the idea that the Congress gave quite a wide interpretation to patent laws**.

[54] 35 U.S. Code, par. 101, Legal Information Institute, Cornell Law School, https://www.law.cornell.edu/uscode/text/35/101
[55] Cambridge University Press, Cambridge Dictionary, 2019, accessed 25 January 2019, https://dictionary.cambridge.org/us/dictionary/english/discovery
[56] U.S. Supreme Court Diamond v. Chakrabarty 1980, Digital Law Online, accessed 25 January 2019, http://digital-law-online.info/cases/206PQ193.htm

The newly created bacteria were rather considered as a "*manufacture*" or "*composition of matter*". **Manufacture** in accordance with Section 101 US Constitution means "*the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labour or by machinery*".[57] And the **composition of matter** was considered as "*all compositions of two or more substances and […] all composite articles, whether they be the results of chemical union, or mechanical mixture, or whether they be gases, fluids, powders or solids*".[58] To support this broad view on subject-matter patentability, I would like to emphasize on the Patent Act 1973 authored by Thomas Jefferson. The Act has embodied Jefferson's philosophy that, "*Ingenuity should receive a liberal encouragement*".[59] Several cases covered the topic of the limits of a patentable subject-matter and enlightened that Section 101 US Constitution should not be interpreted in a way that it has no limits. Indeed, the laws of nature, physical phenomena, and abstract ideas have been held not patentable.[60] A new mineral which was discovered in the nature or a new plant which is wild does not constitute a patentable subject-matter. Like Einstein could not obtain a patent for the law $E=mc^2$, nor could Newton patent the law of gravity.[61] Such phenomena are not human-created or modified, they occur naturally, thus they are discoveries.[62] The Court ruled out that the oil bacteria is a patentable subject-matter, the product of human ingenuity "*[…] which has a distinctive name, character and use*".[63] The patentee has produced a new bacterium with noticeably different features from those which exist in nature and one having the potential for significant utility. This discovery is not considered as the nature's work but as the inventor's own work, therefore it is patentable under section 101.[64] The final ruling made by Warren E. Burger outlined that Congress plainly contemplated that the patent laws should be given wide

[57] American Fruit Growers, Inc. v. Brogdex Co. 1931, FindLaw, 2019, https://caselaw.findlaw.com/us-supreme-court/283/1.html
[58] Deborah E. Bouchoux, *Patent Law for Paralegals* (Delmar, Cengage Learning 2009), https://books.google.be/books?id=47yNKfqzOr0C&pg=PA41&dq=all+compositions+of+two+or+more+substances+and+%E2%80%A6+all+composite+articles,+whether+they+be+the+results+of+chemical+union,+or+mechanical+mixture,+or+whether+they+be+gases,+fluids,+powders+or+solids&hl=ru&sa=X&ved=0ahUKEwj2rbiDisHhAhXNLFAKHZaeAKoQ6AEIKDAA#v=onepage&q&f=false, p. 41
[59] Sreenivasulu, N.S. & Raju, C.B., *Biotechnology and Patent Law. Patenting Living Beings* (Rashtriya Printers India 2008), https://books.google.be/books?id=9-3bWNnOuloC&pg=PA24&lpg=PA24&dq=ingenuity+should+receive+a+liberal+encouragement&source=bl&ots=oC3TsC3vUJ&sig=ACfU3U1l5EI6kiaaiKY4tVZBUxWk3o9SfQ&hl=ru&sa=X&ved=2ahUKEwj2j_aci8HhAhXECOwKHT7QA-EQ6AEwAnoECAMQAQ#v=onepage&q&f=false, p. 24
[60] Parker v. Flook 1978, FindLaw, 2019, https://caselaw.findlaw.com/us-supreme-court/437/584.html
[61] U.S. Supreme Court Diamond v. Chakrabarty 1980, BITLAW, 2019, https://www.bitlaw.com/source/cases/patent/Chakrabarty.html
[62] Funk Brothers Seed Co. v. Kalo Inoculat Co. 1948, FindLaw, https://caselaw.findlaw.com/us-supreme-court/333/127.html
[63] U.S. Supreme Court Diamond v. Chakrabarty 1980, BITLAW, 2019, https://www.bitlaw.com/source/cases/patent/Chakrabarty.html
[64] Ibid.

scope, therefore "*[…] to include anything under the sun that is made by man*".[65] In conclusion, this case as well as other judgments concerning patents granted in respect of living organisms in different jurisdictions, made a big impact on subsequent protection of microorganisms. It is also quite interesting how differently the Patent Office and the Court interpreted the provisions of the law. Notably, the Board of Appeals took a stricter approach and considered that living microorganisms made by a human constituted a part of nature and were not covered by the legislation. Nevertheless, the Court reversed that statement and took a more liberal approach concerning patenting living forms. Personally, I agree with the Court's position because if analyzing the meaning of words "manufacture" and "composition of matter" (what was done in the decision), bacterium, made by a man can be patentable without any questions. It simply cannot be non-patentable just because it is a microorganism and its initial place of existence was known as natural and not synthetic. However, one should take into consideration that unnecessary restrictions placed in patentability of biotechnological inventions may undoubtedly inhibit the technological development. That was done by the Patent Office in Chakrabarty's case but was finally overcome by the Court's decision. At the same time, in pursuit for upholding the Claimant's position, the Court went too far, in my opinion, saying that patent laws should be given such a broad scope that "to include anything under the sun" to a patentable subject-matter. That is a doubtful statement because that was in reality can bring the science and law into precedents in patenting "life itself".

For over than 30 years after decision made by the Supreme Court in the Chakrabarty case, isolated DNA sequences were considered as patentable.[66] In **Myriad I** it was doubted that isolated DNA cannot be patentable because it is a product of nature, ***"the unaltered information-encoding function of DNA"***.[67]

In 1994 genetic scientists from Utah University together with **Myriad Genetics** isolated two DNA sequences as BRCA1 and BRCA2 which indicated the holder's hereditary susceptibility to ovarian and breast cancer.[68] All in all, the company spent around $500 million for 17 years of work to study and isolate these two mutation genes and relate them to the cancer

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[65] Ibid.
[66] Susan, Fletcher French & Gerald, Korngold, *Cases and Text on PROPERTY* (Wolters Luwer New York 2019), https://books.google.be/books?id=TZ6HDwAAQBAJ&pg=PA259&lpg=PA259&dq=For+over+than+30+years+after+decision+made+by+the+Supreme+Court+in+the+Chakrabarty+case,+isolated+DNA+sequences+were+considered+as+patentable&source=bl&ots=GxzMEx65LS&sig=ACfU3U1l0wzAFLT2gu5nmqGNC-nxgVz-EQ&hl=ru&sa=X&ved=2ahUKEwj6ksiLkcHhAhVSbVAKHaCKDH4Q6AEwCHoECAkQAQ#v=onepage&q&f=false, p.259
[67] Stephen H., Schilling, *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* 2011, Vol. 61:731, accessed 26 January 2019, https://pdfs.semanticscholar.org/1521/e33a4d35ec8010655b40ec463ce90f02a63f.pdf (2011).
[68] Raidt, John. "Patents and biotechnology". *US Chamber of Commerce Foundation*. 2014. P. 25. https://www.uschamberfoundation.org/sites/default/files/article/foundation/RaidtPaper.pdf

disease.[69] The USPTO granted Myriad a bunch of patents, thus giving to this company a full monopoly on diagnostic testing for the particular mutations of claimed genes.[70] In 2009 the plaintiff brought a lawsuit against Myriad Genetics as well as against the USPTO, challenging the validity of claims set in 7 patents related to BRCA.[71] The grounds for plaintiff's claim made the lawsuit very controversial because this granted monopoly could have ruined scientific development by virtue of genetic preventing researchers to continue their work with related genes as well as the price for R&D was considered too high.[72] The main plaintiff's statement was that *methods of gene isolation* can be patentable whereas *DNA sequences* whether isolated or not – cannot be eligible to patenting as it is a mere "product of nature".[73] *Isolated* the gene is regarded according to Myriad as deprived of junk elements, doubled by human intervention.[74] Thus, Myriad considered that BRCA1 and BRCA2 cannot be considered as a naturally occurring and the patents granted should have remained valid. John Raidt explains this position from the perspective of already granted patent for adrenalin in ***Parke-Davis Co. v. H.K. Mulfold 1912*** case. But, indeed, there was a list of cases where patents were granted and courts decided in favour of inventors to upheld the existing patents. Thus, in Parke-Davis case the Court explained that the substance which is isolated from the natural environment could be definitely protected under the patent law.[75] The same idea was previously mentioned which was upheld by the court ***In re Bergstrom 1970*** case. *But the outcomes of the Myriad case were different*. The case itself was very controversial and covered by a flow of emotions in the public. Mostly, the society was conscious how a company can hold something that we inherit from our predecessors.[76] The District Court's decision was unambiguous that all opposed claims are invalid.[77] However, the Court of Appeals had a different view on the subject and overturned the decision previously made by the District Court. It was stated that the DNA sequences which do not exist in nature,

[69]Ibid. P. 25
[70] Ibid. P. 26
[71] Weiwei, Han, *Comparative Analysis of Patenting Biotechnological Inventions in the U.S., Europe, Japan and China* (Master Thesis, Munich Intellectual Property Center, 2011-2012), P. 14, https://poseidon01.ssrn.com/delivery.php?ID=608092126118023025125065086021112094059092037020027043122087109090122097076119015118007114061061050022034100119002120003089099023006066082083000127085111103072075096010048051118106120087086018105074029121084121070122027096099115027004011082090068119013&EXT=pdf
[72] Raidt, John. "Patents and biotechnology". *US Chamber of Commerce Foundation*. 2014. P. 26. https://www.uschamberfoundation.org/sites/default/files/article/foundation/RaidtPaper.pdf
[73] Ibid., P. 26
[74] Amelia, Rinehart, *Myriad Lessons Learned*, University of Utah, 2015, https://dc.law.utah.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1015&context=scholarship, p. 4
[75] Raidt, John. "Patents and biotechnology". *US Chamber of Commerce Foundation*. 2014. P. 26. https://www.uschamberfoundation.org/sites/default/files/article/foundation/RaidtPaper.pdf
[76] Jim, Dwyer, In Patent Fight, Nature 1, Companies 0, *The New York Times*, March 30, 2010, https://www.nytimes.com/2010/03/31/nyregion/31about.html?ref=myriadgeneticsinc&_r=0
[77] Ass'n for Molecular Pathology v. USPTO 2010, League, 2017, https://www.leagle.com/decision/infdco20100330948

can be patented. This idea was supported by the decision in Chakrabarty case.[78] **The final decision of the U.S. Supreme Court was univocal:** DNA which was solely isolated from a living organism cannot be considered as an invention and, thus, patentable; however, if it is about a cDNA, (so-called complementary deoxyribonucleic acid), then it can be considered as patent eligible.[79] This case at first glance might look a bit controversial and in a way inconsistent from the practice established in previously observed decisions. Here the Court denied the patents granted to DNA sequences on the ground that they cannot constitute a part of human's ingenuity and were simply isolated from the living organism. Again, one can see that the unspoken recourse was made to the distinction between a mere discovery and an invention. At the time when the defendant claimed that "isolated" can be regarded as "purified", the Court stated that these two notions are not the same in meaning. I agree with the Court's position because isolated and purified should go together but not substitute each other. What is isolated simply from a living organism cannot be patentable because there is no human scientific input into it. Thus, it is just impossible to find out all necessary criteria for patentability in such a case.

Another important case in regards with the patentable subject-matter issue was the ***Mayo Collaborative Services v. Prometheus Laboratories, Inc. 2012.*** The Claimant bought and used special diagnostic tests which were based on patents obtained by Prometheus Inc. Patents were granted for thiopurine medicine for the autoimmune diseases.[80] ***"When ingested, the body metabolizes the drugs, producing metabolites in the bloodstream. Because patients metabolize these drugs differently, doctors have found it difficult to determine whether a particular patient's dose is too high, risking harmful side effects, or too low, and so likely ineffective"***.[81] In 2004 Prometheus sued Mayo Services for infringement of its patents because the latter decided to create its own diagnostic test. The dispute reached the Supreme Court which ruled out that the "*Patents effectively claimed the underlying laws of nature themselves, and thus were invalid*".[82] Moreover, it was considered that those patents just interpret the laws in nature, i.e. the connection between the metabolites concentrations in blood and a possibility that the drug dosage of thiopurine will prove its ineffectiveness or cause injuries.[83] This case differs from what was described before as it deals with the test, in other words, method of determining patients'

[78] John, Conley & Dan, Vorhaus, *Pigs Return to Earth: Federal Circuit Reinstates Most – But Not All – of Myriad's Patents*, The Privacy Report, July 31, 2011, https://theprivacyreport.com/2011/07/31/pigs-return-to-earth-federal-circuit-reinstates-most-but-not-all-of-myriads-patents/#more-6120
[79] Association for Molecular Pathology et Al. v. Myriad Genetics, Inc. et Al. 2013, https://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf
[80] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 2012, https://www.crowell.com/files/Mayo-Collaborative-Services-v-Prometheus-Laboratories-Inc.pdf
[81] Ibid.
[82] Ibid.
[83] Mayo, 132 S. Ct. at 1296. Jeremy, McKinney, "It's a Trap": cDNA is Patent Eligible? But is it patentable?, 2014, https://digitalcommons.law.ou.edu/cgi/viewcontent.cgi?article=1011&context=okjolt

reactions to the drug. The main question here is whether a *diagnostic method* can be considered as patentable or not. I would rather support the opponents of the decision made by the Supreme Court which claim that such a ruling can only stop the development in clinical trials in this sphere as well as the R&D in total. In this respect I would like also to mention words of Gene Quinn, a famous US patent attorney, who wrote: "*How long will it take the Federal Circuit to overrule this inexplicable nonsense? The novice reader may find that question to be ignorant, since the Supreme Court is the highest court of the United States. Those well acquainted with the industry know that the Supreme Court is not the final word on patentability, and while the claims at issue in this particular case are unfortunately lost, the Federal Circuit will work to moderate (and eventually overturn) this embarrassing display by the Supreme Court*".[84] This bold statement gives a clear understanding that there is much to think about of this case. I support the idea that only by attacking other criteria (when subject-matter is almost impossible to dispute) is a dubious way to proclaim patents invalid. In this case it was obvious that there was no reasonable ground to dispute about the subject-matter that is why the explanation that it was "*an interpretation of rules of nature*" is at least not sufficient. If subsequently such decisions become a normal practice in patent litigation the whole system could possible lose its value and sense. A lot of companies might let their billions of dollars go just because of non-meticulous courts' decisions.

Another prominent case in biotechnology is ***Amgen, Inc. v. Chugai Pharmaceutical Co. 1991***. In Amgen, three biotechnological companies struggled against each other to obtain patent for EPO protein which helps to produce blood cells (so-called erythropoietin). The main claim regarded "*A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin*".[85] Used words "*purified and isolated*" relate to the DNA, it was identified and subsequently reproduced not naturally.[86] However, the District Court did not accept such statement and outlined that human EPO is "*nonpatentable natural phenomenon free to all men and reserved exclusively to none*".[87] In 1991 Federal Circuit had acquiesced in the proposition that the words "*purified*" and "*isolated*" were sufficiently to distinguish a claimed gene from its naturally occurring counterpart. Namely, from the words which were used in a

[84] Gene, Quinn, Killing Industry: The Supreme Court Blows Mayo v. Prometheus, *IP Watchdog*, March 20,2012, http://www.ipwatchdog.com/2012/03/20/supreme-court-mayo-v-prometheus/id=22920/

[85] DNA sequences encoding erythropoietin, USPTO Patent Full-Text and Image Database, accessed 2019 April 9, http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=4,703,008.PN.&OS=PN/4,703,008&RS=PN/4,703,008

[86] John, M. Conley, Gene Patents and The Product of Nature Doctrine, 2008, p. 116, https://scholarship.kentlaw.iit.edu/cgi/viewcontent.cgi?article=3638&context=cklawreview

[87] Amgen Inc. v. Chugai Pharm. Co., 13 U.S.P.Q.2d 1737, 1759 (D. Mass. 1989) (quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)). Ibid. P. 116

claim, the essence of the invention in question *was the cloning of EPO gene*.[88] Thus, the clone itself does not constitute a naturally-occurring gene but only a complementary DNA (cDNA) which is not similar to what exists in human's body. "*cDNA is a faithful reverse transcription of sequence recorded by mRNA, it is DNA, not RNA and, thus, a different chemical*".[89] Notably, this case which emphasized on described distinction has become very important in further gene patenting performed by USPTO. Moreover, it gave a possibility for Amgen to continue its research in the procurement of patients who are on kidney dialysis and even provide with license Johnson & Johnson on the whole territory of the USA. One of the relevant claims which backed up Amgen's position is that an EPO protein "*A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin*".[90] This simply explains an idea that a DNA notwithstanding the fact that it is a compound which exists in natural environment, nevertheless can be patentable if "isolated" and "purified". It obtained a special name in biotechnology as a cDNA or in other words – a complementary DNA, which is created by using human's ingenuity by virtue of cloning/genetically modifying a DNA sequence, and is generally recognized as a patentable subject-matter.

A bright example of distinguishing naturally and artificially occurred genes is illustrated in the Skolnik's patent claim regarding breast cancer gene. The word "isolated" plays the same important role in identifying subject-matter of the biotechnological invention. Thus, "isolated" embraces a nucleic acid sequence which has been removed from its naturally occurring environment. It was also stated that isolated gene does not contain any non-coding DNA.[91]

Besides a group of cases which determined inability of patenting living organisms, there were also signed a few legal acts concerning this matter, e.g. a statute *Leathy-Smith America Invents Act (2011)*. This Act stands for the protection of human beings and thus prohibits granting any patent to "*[…] any claim directed to or encompassing a human organism*" (Section 33).[92] The USPTO for quite a long period of time introduced the idea that "*If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S. Constitution par. 101 must be made indicating that the claimed invention is directed to non-statutory subject-matter*".[93]

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[88] Ibid. P.116
[89] Ibid. P.116
[90] United States Court of Appeals,Federal Circuit. AMGEN, INC., Plaintiff/Cross-Appellant, v. CHUGAI PHARMACEUTICAL CO., LTD., and Genetics Institute,Inc., Defendants-Appellants 2016, OpenJusrist, https://openjurist.org/927/f2d/1200/amgen-inc-v-chugai-pharmaceutical-co-ltd
[91] Ibid.
[92] Leahy-Smith America Invents Act, WIPO Lex, https://wipolex.wipo.int/en/text/238777
[93] The Leahy-Smith America Invents Act, Office of General Counsel, The Catholic University of America, accessed 2019 March15, http://counsel.cua.edu/fedlaw/nacuanotesleahysmith.cfm

Notably, American biotechnology has developed quite rapidly that is why inventors were always seeking for the protection of their technological creations. Notably, that the U.S. Constitution gave such a possibility to scientists by introducing Section 101 and first Patent Act which did not precisely tell anything about exclusions from patent eligibility. However, notwithstanding the fact that the wording of laws appeared to be not that strict, USPTO was not very prone to grant patents to anything what was connected to living organisms. The same was with the courts which mostly ruled out impossibility of "patenting the nature". Such a situation as we see existed almost up to 1980. A historically changing event happened in the U.S. Supreme Court within the decision in Chakrabarty case. In other words, it launched the era when "anything under the sun can be patentable". Society gradually turned its mind to accepting an idea that biological inventions should be patentable in order to promote research and development. Undoubtedly, this prominent case has become a precedent and an "open door" for those who was seeking for the protection of inventions connected to living organisms even including genomes. The USA has also become a state which started a so-called *Human Genome Project in 1988*. It aimed to find out the general understanding of all genes in humans body. The project has indeed become even an international one, a collaborative research.[94] This also emphasizes on the fact that the future development of biotechnology as well as questions about patent eligibility of inventions connected to it have become unavoidable. To my mind, such a rapid development of science and expanding amount of applications to the USPTO evoked a fear that very soon the entire life could become also patentable. Therefore, one can observe that even after the "patent burst" after 1980s, America again encounters several decisions which abandoned patents to DNA sequences explaining that it could not be an invention by virtue of its isolation from the organism (Myriad case example). What is the difference in legal reasoning of Myriad and other similar cases which involved DNA and were considered as patentable, is still not fully understandable (compared for e.g. with Amgen case). However, one fact was and remains precise: cDNA is eligible for patenting in comparison with its clone. The other reason which can explain these differences is the time when those decisions were made (some have difference over 20 years). All in all, the USA is still an example for other countries and its case law in patent law is considered as leading all over the world.

2.2. PATENT ELIGIBILITY IN THE EU

The centralized patenting system which European Union has nowadays, occurred back in 1973 within the adoption of European Patent Convention (EPC). Today 38 Member states and

[94] An Overview of Human Genome Project, NIH, accessed 2019 March 15, https://www.genome.gov/12011238/an-overview-of-the-human-genome-project/

also so-called EU "extension states" (Bosnia and Herzegovina, Montenergo) and "validation states" (Morocco, Moldova, Tunisia and Cambodia) are participants of European Patent Organization (EPO) and are signatories of the EPC respectively.[95] The adoption of EPC became a very important step in the history of patent development in European area and allowed different undertakings to claim protection of their inventions through a single system. The procedure on a whole starting from patent application, examination and ending with granting patents became much more easier and more convenient for those who sought and seek for a protection nowadays. No more inventors had to apply to each of the signatory country to obtain a patent. The time, costs and paperwork has decreased significantly. However, one should bear in mind that despite the fact that the centralized system of patent obtainment was created what, without a doubt, simplified life, it did not, unfortunately, made available, as it was mentioned previously, to get a single EU Patent for every country at once. When an applicant gets a so-called European Patent, it means that he obtains a "bunch of patents" in all countries which were mentioned in a single application. Namely, this system just shows again that IP rights – are territorial rights and every country separately decides whether to grant a protection to a declared invention or not.

Another essential document that I will observe in this work is Directive 98/44/EC on the Legal protection of biotechnological inventions (further – Directive). This legal act was a great step into the promotion of biotechnological inventions by virtue of reducing mismatches in national laws of Member States as well as in administrative issues. It can be proved by the provisions set out in the preamble of the Directive that the "*Differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the different Member States; whereas such differences could create barriers to trade and hence impede the proper functioning of the internal market*".[96] Truly, the adoption of the Directive was a decent attempt to harmonize national laws in respect of patenting biotechnological inventions introducing patentability criteria, scope of protection, compulsory cross-licensing regulation.

EPC in art. 52 describes which inventions can be patentable and names main requirements for that: "European patents shall be *granted for any inventions, in all fields of technology*, provided that they are *new, involve an inventive step and are susceptible of industrial application.*"[97] The first part just names general criteria for patentability but the second paragraph of the same article describes cases when patents shall not be granted because of

[95] EPO, Extention states, 2019, https://www.epo.org/about-us/foundation/extension-states.html
[96] Directive 98/44 EC on the legal protection of biotechnological inventions. Official Journal of the European Communities. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML
[97] The European Patent Convention, art. 52.EPO, https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar52.html

absence of invention itself. These are: **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; presentations of information.[98] Art. 53 EPC covers an excluded scope of the patentability concerning non-patentable subject-matter. Thus, EU patents shall be not given for: "inventions which are contrary to "ordre public" or morality; plant or animal varieties or essentially biological processes for the production of plants or animals; methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body".[99] EPC identifies in the Rule 23b what constitutes a *biotechnological invention*: that are "*inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used*".[100] At the same time this Rule describes what is "biological material" per se: "*any material containing genetic information and capable of reproducing itself or being reproduced in a biological system*."[101]

Rule 27 EPC concretely describes biotechnological inventions and their ability to being patentable. Thus, "biological material which is *isolated from its natural environment* or *produced by means of a technical process,* plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety, a *microbiological or other technical process,* or *a product obtained by means of such a process other than a plant or animal variety can be patentable"*.[102] It should be mentioned that the rule written down in EPC concerning biotechnological inventions is more precise than the understanding of what can be patentable under U.S. law. Moreover, despite the fact that the list of patentable subject-matter in EPC is not exhaustive, still the provision itself gives a clear understanding of what is at the same time excluded from the protection – plant and animal varieties.

It is agreed by the signatory states that biotechnological inventions which can be patentable refer not only to ones produced by means of a technical process but also isolated from its natural environment. This means that EPC directly outlined that what is obtained from natural environment can be patentable, however, there is no precise explanation what is considered to be "isolated from natural environment" – only isolated or isolated and purified? Actually, this question is left open for the interpreter (Patent Offices and courts) and it is in charge to decide the extent of the notion applicability in practice.

[98] Ibid.
[99] Ibid. Art. 53
[100] Ibid. Rule 26
[101] Ibid. Rule 26
[102] Ibid. Rule 27

EPC states that discoveries are not considered to be patentable. American law and in particular courts' decisions not once referred to this question. So what does the European law say about this matter? Art. 52(2)(a) explicitly states that discoveries are not inventions. EPO's opinion about the differentiation of these two notions based on a mixture of them. The first opinion is that the line between an invention per se and a discovery represents "industrial applicability", whereas the second idea is that the discovery always need some human's ingenuity and technical contribution in order to be considered as an invention and the European Patent's Office position best seeable in the decision of Relaxin case made by EPO:

> *To find a substance freely occurring in nature is mere discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. Moreover, if this substance* ***can be properly characterized by its structure and it is new in the absolute sense of having no previously recognized existence****, the substance per se may be patentable. The new Rules 23c(a) and 23e EPC have made this line between discovery and invention even more clear.*[103]

To the excluded scope of patentable inventions also relate: methods for treatment of humans and animals using surgery or diagnostic methods. This is stressed in the art 53(c) of EPC. Previously such methods were regarded as non-industrially applicable that is why excluded from the patent protection. The new version of the article however does not contain this provision any more. "*The methods set out in Art. 52(4) EPC (the new – 53 (c) are excluded from patentability as a matter of policy. This exclusion is not a new provision under the EPC. Before the EPC came into force, such methods were excluded from patentability under the national laws of many European countries. The policy behind the exclusion of such methods was clearly to ensure that those who carry out such methods as part of the medical treatment of humans or the veterinary treatment of animals should not be inhibited by patents*".[104] The main idea of prohibiting such methods for being acceptable for patenting was to prevent non-commercial medical institutions from various obstacles in using therapeutic treatment and diagnosis installed by the rights of patent holders.[105] For example, in Board's decision T385/86, the art. 53(c) (an old version – 52(4) of EPC showed "an exception to the general obligation to patent inventions".[106]

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[103] Sasa, Bavec & Peter, Raspor, Patenting Biotechnological Inventions in Europe, Food Technol. Biotechnol. 40 (4) 353–359 (2002), p. 354, https://www.researchgate.net/publication/288820380_Patenting_Biotechnological_Inventions_in_Europe

[104] Case Law of the Boards of Appeal of the European Patent Office, EPO, page 17, http://legis.obi.gr/espacedvd/clr/clrpdf/en/complete.pdf

[105] Ibid.

[106] Ibid.

Art. 53 (b) also excludes from patentability "plant or animal varieties or essentially biological processes for the production of plants or animals".[107] Changing plants' biologic characteristics has become an essential process in genetic modification. This was launched in order to make them resistant to different illnesses, yeasts and parasites and, thus, protect cops and food.[108] As it was already mentioned, previously humans only were able to change some features of a plant using not sophisticated cross-breeding. According to the Rule 23 (4), a plant variety is "*any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:(a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes,(b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and (c) considered as a unit with regard to its suitability for being propagated unchanged*".[109] The underlying logic in prohibition of patenting plant varieties is that it helps to avoid double protection of them in states which allow to obtain protection under the system introduced by the Union for the Protection of New Varieties of Plants (UPOV).[110] In Rule 23 b (5) is mentioned that, "*a process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection*."[111] It can be also explained by the fact that many years ago breeders tried to create different plant varieties by virtue of random manner in order to obtain something different.[112] Indeed there was no a precise process of genetic modification but only endeavors of breeders to get a new plant; that is why, when EPC was drafted, it was decided that such plant lack technical feature and thus cannot be patentable but at the same time can be protected by a Plant Variety Right.[113] But of course within the growth of technology, it became much more easier to get desired features of plants by means of transgenic manipulations (inserting an alien gene into a host plant). The Technical Board of EPO has encountered with situations of plant patentability. For example, in Novartis/Transgenic Plant case the main patent claim concerned an inserted foreign genome into a plant in order to improve the features of the latter; the EPO

[107] The European Patent Convention, art. 53(b), EPO, https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar53.html
[108] Biotechnology Patents at the EPO, EPO, 2017, https://www.epo.org/news-issues/issues/biotechnology-patents.html
[109] The European Patent Convention, rule 23, EPO, https://www.epo.org/law-practice/legal-texts/html/epc/1973/e/r23b.html
[110] Sasa, Bavec & Peter, Raspor, Patenting Biotechnological Inventions in Europe, Food Technol. Biotechnol. 40 (4) 353–359 (2002), p. 355, https://www.researchgate.net/publication/288820380_Patenting_Biotechnological_Inventions_in_Europe
[111] The European Patent Convention, rule 23, EPO, https://www.epo.org/law-practice/legal-texts/html/epc/1973/e/r23b.html
[112] Biotechnology Patents at the EPO, EPO, 2017, https://www.epo.org/news-issues/issues/biotechnology-patents.html
[113] Ibid.

rejected the registration of a plant on the ground of art. 53b EPC.[114] However, the Board of Appeal reversed this decision on the ground of analysis what constitutes a plant variety under UPOV Convention and EC Regulation on Plant Variety Rights.[115] At the same time it identified that "plant defined by a single recombinant DNA sequence "is not an individual plant grouping to which an entire constitution can be attributed."[116] Thus, it was quite important that the plant itself was genetically modified and not simply constituted a plant group in order to obtain patent protection.

Biotechnology Directive sets in art. 4 that plant and animal varieties shall not be patentable, however, in paragraph 2 it is stated that, "*inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety*."[117] It should be also mentioned that there is a clear correlation between a patent and a breeder's right. In reality, there might be a situation when a breeder of a new plant variety can simply infringe already existing patent right, thus, in such a case Biotechnology Directive stipulated such a phenomenon as "compulsory cross-licensing".[118] In paragraph 1 art. 12 of the Directive is written: "*Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the patent will be entitled to a cross-license on reasonable terms to use the protected variety*."[119] This article simply allows a breeder to avoid a possible infringement only when indeed he cannot get or use his rights without breaching the rights of a patent holder. As it is noticeable from the provision – such license should be non-exclusive and in extent which is necessary to use breeders' rights. Interestingly, in 2009 the Dutch association for breeding, tissue, culture, production and trade of seeds and young plants, Plantum NL, declared its opinion concerning the relation between breeders' rights and patents, and in particular, it stated that there must be "*free availability of the biological materials* that are already protected as inventions, as well as *their free use and, mainly, that such exploitation cannot be in any way obstructed by already existing patent*

[114] Michael, Blakeney, "Patenting of Plant Varieties and Breeding Methods", *Journal of Experimental Botany*, Volume 63, Issue 3, February 2012, Pages 1069–1074, https://academic.oup.com/jxb/article/63/3/1069/473047
[115] Ibid.
[116] Ibid.
[117] Directive 98/44 EC on the legal protection of biotechnological inventions. Official Journal of the European Communities. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML
[118] Michael, Blakeney, "Patenting of Plant Varieties and Breeding Methods", *Journal of Experimental Botany*, Volume 63, Issue 3, February 2012, Pages 1069–1074, https://academic.oup.com/jxb/article/63/3/1069/473047
[119] Directive 98/44 EC on the legal protection of biotechnological inventions. Official Journal of the European Communities. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML

rights".[120] To my mind, such a position obviously stands more for the protection of breeders, not the patent holders. There might arise a question, namely, to which extent such availability is regarded as "free" and what is the way to get access to such biological materials because such frivolous formulation can bring patent holders and breeders to a court dispute arguing about that border of freedom. Also, there is a question which relates to further breeding of already existing plant varieties consisting of patented technical feature. Actually, this matter is also covered by a professor Michael Blakeney in one of his works, in particular, he says that a lot of top companies in technology with quite strong patent portfolios started to claim the prohibition of further using a plant which was breed by using a protected patent right.[121] Obviously, the only result which can be obtained in such case – is the large-scale deliberate infringement of patents; in this situation potential infringers can just hide behind the before mentioned free wording regarding correlation between patent rights and breeding.

In this respect I would like also to cover another important issue which relates both to plants and animals – **essential biological processes** which also cannot be patentable under European law. Under the Biotechnology Directive microbiological process is defined as "*any process involving or performed upon or resulting in microbiological material.*"[122] The same definition can be as well found in the EPC in Rule 23.

In the Commission Notice on certain articles of Directive 98/44/EC 2016, it was noticed that in March 2015 the Enlarged Board of Appeal (EBA) of the EPO made a statement that all products, in principle, which are obtained from "essential biological process" can be patentable even though such process was "essentially biological", e.g. using selection method.[123] Of course, this statement was not in the line with the legal regulation provided for plant or animal varieties.[124] But Directive is silent whether animals or plants obtained through such a process can be patented or not.[125] But when analyzing the logic of the European legislator, the Commission came to conclusion that at the time of Directive's drafting the initial idea was to prohibit the patentability of any kind of products obtained due to essentially biological process:

> *Essentially biological procedures, i.e. crossing and selection of the whole genome […] do not meet the general conditions for patentability, as they are neither inventive nor reproducible. Breeding is a reiterative process, in*

[120] Michael, Blakeney, "Patenting of Plant Varieties and Breeding Methods", *Journal of Experimental Botany*, Volume 63, Issue 3, February 2012, Pages 1069–1074, https://academic.oup.com/jxb/article/63/3/1069/473047
[121] Ibid.
[122] Directive 98/44 EC on the legal protection of biotechnological inventions. Official Journal of the European Communities. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML
[123] Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions. Official Journal of the European Union. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XC1108%2801%29
[124] Ibid.
[125] Ibid.

which a genetically stable end-product with the required characteristics is attained only after much crossing and selection. This process is so strongly marked by the individuality of the initial and intermediate material that an identical result will not be obtained upon its repetition. Patent protection is not appropriate for such procedures and their products.[126]

The attitude towards this issue was also set in the cases known as Broccoli (Patent EP1069819, year 2002[127]) and Tomato (Patent EP1211926, year 2000[128]). In the first case there was an issue whether the **biological process of cross-breeding** can be patentable and the second situation referred to cross-selection of tomatoes respectively.[129] It derives from the main patent claim of the broccoli patent that the method was developed "for selective increase of the anticarcinogenic glucosinolates"[130] in the plant. In more simple words, scientists endeavored to increase the selectiveness of a special material in a vegetable which would reduce the potential cancer danger among humans.[131] The second patent claim (Tomato case) introduced a vegetable with the decreased level of fruit water in it again by the use of breeding technical method.[132] EPO considered both of these methods as patentable but after that decision these patents were attacked by the opponents who claimed the methods to be "essentially biological" and thus unpatentable.[133] EPO tried to figure out what is indeed envisaged under EPC as "essentially biological process" and found the provision set in Biotechnology Directive rather ambiguous: "*On the one hand, only processes which* ***consist entirely of natural phenomena*** *are considered to be essentially biological process for the production of plants. On the other hand, crossing and selection are given as examples of natural phenomena. This appears to be self-contradictory to some extent since the systematic crossing and selection carried out in traditional plant breeding would not occur in nature without the intervention of man.*"[134]

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[126] Explanatory statement to the ROTHLEY report, 25 June 1997 (A4-0222/97), p. 38, footnote 5. Ibid.
[127] The Word is Out: Patenting Plant Breeding Methods, Ipeg, access 2019 March 29, https://www.ipeg.com/the-word-is-out-patenting-plant-breeding-methods/
[128] Ibid.
[129] Michael, Blakeney, "Patenting of Plant Varieties and Breeding Methods", *Journal of Experimental Botany*, Volume 63, Issue 3, February 2012, Pages 1069–1074, https://academic.oup.com/jxb/article/63/3/1069/473047
[130] Claims EP1069819 (A1), Espacenet, EPO, 2017, https://worldwide.espacenet.com/publicationDetails/claims?DB=&ND=3&locale=en_EP&FT=D&date=20010124&CC=EP&NR=1069819A1&KC=A1&tree=false
[131] Prabhakaran, Soundararajan & Jung Sun Kim, *Anti-Carcinogenic Glucosinolates in Cruciferous Vegetables amd Their Antagonistic Effects on Prevention of Cancers*, Molecules. 2018 Nov; 23(11): 2983. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6278308/
[132] EP1211926 (A1), Espacenet, EPO, 2017, https://worldwide.espacenet.com/publicationDetails/biblio?II=0&ND=3&adjacent=true&locale=en_EP&FT=D&date=20020612&CC=EP&NR=1211926A1&KC=A1
[133] The Word is Out: Patenting Plant Breeding Methods, Ipeg, access 2019 March 29, https://www.ipeg.com/the-word-is-out-patenting-plant-breeding-methods/
[134] Ibid.

Personally, I accept this remark because crossing and selection in breeding cannot be definitely considered as natural only by virtue of using natural material for further manipulations. Plant breeding is defined by itself as a manipulation which can involve genetic engineering or pollination or both to create new plant species.[135] This definition explicitly shows the correctness of EPO approach.

The difficulty in determining the real meaning hidden in the words brought this question to the Enlarged Board of Appeal (EBA) which emphasized that breeding methods that are made exclusively by virtue of using technical instruments will never be considered as of technical nature.[136] Moreover, the EBA explained its position from the historical point of view of development of art 53 EPC: the idea was to exclude from patentability mere conventional breeding methods for new plant varieties.[137] I agree with the position of EBA in determining what constitutes a technical feature in a new invention. It is known that before analyzing an invention for novelty, inventive step and industrial applicability, the EPO and the applicant at first should be sure that they deal with an invention per se. And invention is always something technical, something that falls into the scope of any field of technology, therefore one can see that **aesthetic creations, mathematical methods, presentations of information, schemes, rules etc. are excluded from patentability by law because they are simply not of the technical nature.** I entirely agree with the position that technical tools in breeding cannot bring this feature to a process in order to make it able to patentability. It is indeed clear what guided EBA to make such a conclusion. *Rule 28 (2) EPC* says that "*EU patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process*".[138] EPO explains this provision as it is prohibited to give patents for listed inventions exclusively obtained from the essential biological process, thus, by non-technical means.[139] Technical feature appears only when there is a "*direct intervention in the genome of the plants or animals*".[140]Also EPO in its deliberations addresses to the interpretation of the word "exclusively". To its mind, it should be considered as any animal or plant which derives from a technical process – does not fall under the excluded scope of article 53 EPC.[141] The mere conclusion is that genetically modified organisms whether they are animals or plants – are patentable whereas those that are obtained by a usual breeding – not.[142] What was also useful

[135] Plant Breeding, *Science Daily*, accessed 2019 March 31, https://www.sciencedaily.com/terms/plant_breeding.htm
[136] Ibid.
[137] Ibid.
[138] The European Patent Convention, rule 28, EPO, https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/r28.html
[139] Guidelines for Examination, EPO, https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_4.htm
[140] Ibid.
[141] Ibid.
[142] Ibid.

from the side of EBA, is that it has set the criteria how to determine that a process is NOT essentially biological:

1) Entire human involvement into the process and results coming out of it;
2) The intervention must be determined;
3) The contribution must be made not in a usual way;
4) That must be evaluated according to the importance of an invention.[143]

One more exclusion from patentability which is inserted into article 53 (b) EPC, is the prohibition of obtaining exclusive rights on inventions connected to animal varieties. In EPO case law the board several times approved non-ability of certain kinds of animals which are non-patentable but also emphasized that it does not relate to all animals on a whole.[144] In case T 19/90 (1990) the board also stated that when interpreting the notion "animal varieties", the interpretation itself must be narrow and it is not an obstacle to obtain a patent to an invention which does not cover "animal varieties", "Tierarten".[145] In case T 315/03 (2006) some opponents stated that genetically modified mouse could be considered as a new kind of species because it **inherited one precise feature** that showed the possibility of increasing growth of tumors, however the board did not agree with such considerations because it was merely not enough to create new species.[146] Generally, the ground for the exclusion of animal varieties from patentability as well as those which were obtained by virtue of essentially biological process without a trace of technical intervention – is the same, that is why namely rules and cases which apply to plants – apply in the same way to animals.

[143] Michael, Blakeney, "Patenting of Plant Varieties and Breeding Methods", *Journal of Experimental Botany*, Volume 63, Issue 3, February 2012, Pages 1069–1074, https://academic.oup.com/jxb/article/63/3/1069/473047
[144] Case Law of the Boards of Appeal, EPO, 2016, https://www.epo.org/law-practice/legal-texts/html/caselaw/2016/e/clr_i_b_3_2.htm
[145] Ibid.
[146] Ibid.

3. ETHICAL AND MORAL ASPECTS IN BIOTECHNOLOGICAL INVENTIONS

3.1. GENERAL OVERVIEW OF MORALITY IN PATENTING

Despite the fact that biotechnology as a separate field of science has already existed for more than 40 years, there are still a lot of issues concerning new inventions nowadays. Questions related to such inventions are highly debatable not only in scientific area. Society and, in particular, lawyers are actively involved in discussing of these questions and even fulfill a role of a watchdog to protect both public and private interests. Oliver Mills emphasizes that the rapid development of technology as well as of the science on a whole makes it problematic to regulate biotechnology matters legally because law and case law are simply slower than the development of legal relations which exist and emerge in the society.[147] Scientists are namely able to find out how the technology will develop and grow in the future whereas lawyers should define how at the same time to protect rights and interests of the society as well as of other undertakings. It is also important to note that scientists are not able in a full amount evaluate the possible danger of their activity, especially in ethical and moral aspects because they firstly think of positive input in advancement of the technology and only then about dangerous effects of their activity.[148]

The main problem that there are a lot of objections to biotechnology itself and of course to the inventions related thereof.[149] And the main objective – are moral and ethical concerns. ***Bioethics*** is a well-known field in science that deals with ethical applications of health-related life sciences and therapeutic treatment.[150] This field of study has philosophical roots and more relates to the decision-making process on different levels of its application.[151] Darryl R. J. Macer makes an example how such a decision-making is conducted: for example, in the medicine, on a personal level it describes a relation between a patient and medical staff, and at the higher level this can involve other participants too.[152] What is also important – to differentiate between *ethics* and *morality*. It is widely known that *morality* is a bunch of norms, ideas and values which are considered valid among the individuals of a particular society and serve a as guideline for the behavior of each member of the society. Moreover, morality serves as a basis for law during its

[147] Oliver, Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (Routledge, New York, 2016), p. 1
[148] Julian Kinderlerer and Diane Longley, "Human Genetics, the new Panacea?", 1998, vol. 61, Modern Law Review, 603-620 at 604.Oliver Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (Routledge, New York, 2016), p. 1
[149] Oliver, Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (Routledge, New York, 2016), p. 1
[150] "What is Bioethics?", Center for Ethics and Humanities in the Life Sciences, Michigan State University, accessed 2019April 1, https://www.bioethics.msu.edu/what-is-bioethics
[151] Darryl R. J. Macer, "Biotechnology and Bioethics: What is Ethical Biotechnology?", *Modern Biotechnology: Legal, Economic and Social Dimensions, Biotechnology,* Volume 12, ed. D. Brauer (Weinheim, Germany: VCH, 1995), p. 115-154, http://www.eubios.info/Papers/VCH.htm
[152] Ibid.

creation, application and interpretation, that is why moral values despite their non-obligatory force have a high significance for legal sphere.

Moral norms were the first which appeared among the members of society therefore they are namely built on a public opinion. At the same time *ethics* as a branch in philosophy and thus cannot be defined the same as morality. Of course, in many cases what is immoral can be recognized also as unethical, however it is still not the same. The main distinction in these two notions that morality always refers to a particular circle, starting from personal moral settings whereas ethical norms encompass a broader understanding what is moral or not in generally not only for a particular individual or a society. The Technical Board of Appeal of EPO found out that there is no any definition in European law as "*morality*" and it means only means "*a belief that some behavior is right whereas other behavior is wrong, this belief being founded on the totality of accepted norms which are deeply rooted in a particular culture which, in the case of EPC, is the culture inherent in European society and civilization*".[153]

So what causes society to introduce moral restrictions against biotechnology in law? There are various reasons for that, in particular: unethical, immoral attitude, playing with God considerations, undesired hazardous outcomes for environment, health effects, genetic mutations, cloning, embryo usage, fear of unknown outcomes.[154] To such objections also refer ideas that genes are the common heritage of humanity and should be transferred from one generation to another without any interventions conducted by the science.[155] Interestingly, the history of development of patent law shows that in the USA courts were eager to save the rights granted for so-called "immoral" patents which fell into the scope of two main areas: inventions which defraud consumers and tools for gambling.[156] In contrast to the USA law, the European law has specified restrictions in patentable subject-matter inventions. Patents in biotechnology raised a lot of concerns about what is moral and what is not. In particular, the introduction of provisions prohibiting to protect what is "immoral" and against the "ordre public" was caused by the active opposition of various NGOs as Greenpeace which were concerned about "owning the life"

[153]Decision T.356/93 Plant Genetic Systems, PGS. Andrea, Radonjanin, "Patentabiliy of Biotechnology: Does Article 6 of the Biotech Directive introduce a single European concept of morality in patent law?", Evropski Pravnik 2007, https://www.academia.edu/8109126/PATENTABILITY_OF_BIOTECHNOLOGY_Does_Article_6_of_the_Biotech_Directive_introduce_a_single_European_concept_of_morality_in_patent_law

[154] Darryl R. J. Macer, "Biotechnology and Bioethics: What is Ethical Biotechnology?", *Modern Biotechnology: Legal, Economic and Social Dimensions, Biotechnology*, Volume 12, ed. D. Brauer (Weinheim, Germany: VCH, 1995), p. 115-154, http://www.eubios.info/Papers/VCH.htm

[155] Oliver, Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (Routledge, New York, 2016), p. 13

[156] Ibid, p.6

possibility.[157] The USA patent law does not contain specific restrictions connected to abuse of morality, moreover, courts mostly took quite a liberal position to protect advancement in technology. A bright example can be an extract from the Congresses' hearings in Charkrabarty case where it stated that, "**Patent law is not the place to exercise moral judgments about scientific activity**".[158] This statement explicitly shows the attitude of the legislator towards patentability of biotechnology and if we address to various cases in the US courts, mostly they are about disputing not a subject-matter but novelty and inventiveness. Of course, it is still a question whether such a radical approach is reasonable enough for many people but I personally consider the USA position to be sound because morality and ethics are not legal notions and are of a highly subjective understanding therefore create a lot of uncertainty in legal sphere what is unacceptable.

It was already mentioned that patent laws are territorial by nature that is why there is still no one general patent which can be enforced in all designated countries at the same time. However, globalization in the world keeps on growing and, despite the fact that even moral and ethical restrictions must be purely of national character, some laws of international/regional character concern every country which has assigned to them. EPC has introduced art 53(a) which prohibited granting patents to inventions "the commercial exploitation of which would be contrary to ordre public" or morality".[159] Rule 28 of EPC refers to this article and prohibits biotechnological inventions in *all manipulations with human beings such as cloning, modifications of germ lines, using human embryos*.[160] Firstly, EPO emphasized that the considered article should be interpreted narrowly and applied in "rare and extreme cases".[161]

However, in Europe the morality issue had rather a limited extent until the fast development of biotechnology itself started: as in the USA, the debates began at the level of patenting microorganisms and then expanded up to higher living forms e.g. DNA sequences.[162] EPC was not the only legal document which highlighted the problem of ethics in biotechnology patents; it was also a Biotechnology Directive 98/44/EC which has a special provision regarding

[157]Peter, Drahos, Biotechnology Patents, markets and morality, European intellectual property review 21(9):441-449 · January 1999, p. 4, https://www.researchgate.net/publication/299535169_Biotechnology_patents_markets_and_morality
[158] Ronald Schapira, "Biotechnology patents in the United States", in Biotechnology, Patents and Morality n. 3 above, pp.171, 172. Ibid, p.4
[159] The European Patent Convention, art.53, EPO, https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar53.html
[160] Ibid. Rule 28
[161]EPO guidelines C-IV,3.1. Peter, Drahos, Biotechnology Patents, markets and morality, European intellectual property review 21(9):441-449 · January 1999, p. 4, https://www.researchgate.net/publication/299535169_Biotechnology_patents_markets_and_morality
[162] Andrea, Radonjanin, "Patentabiliy of Biotechnology: Does Article 6 of the Biotech Directive introduce a single European concept of morality in patent law?", Evropski Pravnik 2007,https://www.academia.edu/8109126/PATENTABILITY_OF_BIOTECHNOLOGY_Does_Article_6_of_the_Biotech_Directive_introduce_a_single_European_concept_of_morality_in_patent_law

morality (art. 6): "*Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation*".[163] At the very beginning this Directive did not contain any norms concerning ethical aspects that is why actually the Green Party began a campaign neglecting a legal act concerning biotechnology patents without relevant moral restrictions.[164] Notwithstanding the fact that the relevant changes were embodied into the Directive's draft, still the EU Parliament did not consider this document to be that *effective*.[165] Notably, art. 7 of the Directive mentions The Commission's European Group on Ethics in Science and New Technologies which is in charge of evaluation **of the ethical aspect in biotechnology**.[166] Nowadays the Group acts independently and gives various opinions to Commission regarding moral and ethical aspects with the view on rapid development of technology and scientific researches.[167]

Art 6.1 Biotechnology Directive indeed does not give any new input in already existing moral restrictions placed in the EPC in art. 53, however, in the decision ruled out by the EU Court of Justice in case ***Netherlands v. European Parliament and Council*** was stated that the first paragraph of **the relevant article gives a room for Member States to decide themselves on the excluded scope in their national patent laws**.[168] The case law of EPO gives an insight into quite a narrow interpretation of the article 6 of Biotechnology Directive and the application of the morality concept itself is more cautious than straightforward.[169] Although EPO did not create an understanding of a general moral concept throughout its practice, still, it is pretty noticeable that the interpretation of article 6 of Biotechnology Directive has indeed expanded.[170] According to the EPO Guidelines, in order to exclude an invention from patentability, it must be out of tune with the public order that its patenting will be considered unacceptable by the

[163] Directive 98/44 EC on the legal protection of biotechnological inventions. Official Journal of the European Communities. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML
[164]Andrea, Radonjanin, "Patentabiliy of Biotechnology: Does Article 6 of the Biotech Directive introduce a single European concept of morality in patent law?", Evropski Pravnik 2007,https://www.academia.edu/8109126/PATENTABILITY_OF_BIOTECHNOLOGY_Does_Article_6_of_the_Biotech_Directive_introduce_a_single_European_concept_of_morality_in_patent_law
[165] Ibid.
[166] Directive 98/44 EC on the legal protection of biotechnological inventions. Official Journal of the European Communities. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML
[167] European Group on Ethics in Science and New Technologies, European Commission, accessed 2019 April 1, https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/european-group-ethics-science-and-new-technologies-ege_en
[168] Case C-377/98 Netherlands v. European Parliament and Council. Andrea, Radonjanin, "Patentabiliy of Biotechnology: Does Article 6 of the Biotech Directive introduce a single European concept of morality in patent law?", Evropski Pravnik 2007,https://www.academia.edu/8109126/PATENTABILITY_OF_BIOTECHNOLOGY_Does_Article_6_of_the_Biotech_Directive_introduce_a_single_European_concept_of_morality_in_patent_law
[169]S. H.E. Harmon, "From Engagement to re-engagement: the expression of moral values in European patent proceedings, pas and future", 2006. Ibid.
[170] Ibid.

society.[171] I cannot agree that the wording of the provision embedded in paragraph 1 art. 6 gives Member States a larger room to interpret what can be excluded from patentability because the second paragraph of the same article gives a straightforward understanding what should be definitely prohibited as an invention. Moreover, it is a question how Patent Offices and subsequently courts will be able to measure the level of acceptability of an invention in society in order to decide whether it contradicts moral norms or not.

3.2. MORAL DEBATE IN ANIMAL-RELATED PATENTS

Morality issue in animal kingdom calls upon the idea that clinical trials on animals and genetic interference into their organisms cause them to suffer. Oliver Mills states that the idea of protecting animals is one-sided and has nothing to do with moral evaluation because decisions taken on ethical basis "involve a continuous accommodation of conflicting values".[172]

Attention should be also drawn to some provisions related to isolated biological parts from living organisms. In this case I would like to address to some provisions which are set in Biotechnology Directive as well as in EPC. Directive 98/44 allows to patent biological material which is "isolated from its natural environment" (par.2 art. 2). Of course, the initial biological material which is widely used biotechnology and constitute its basis – is a DNA sequence. In the USA an abundant case law primarily allows cDNa to be patentable or those DNA which were "isolated" and "purified". European legislator has relatively the same vision on the patentability of genomes and chemical sequences as the USA. It is stated in par. 2 art. 5 of Biotechnology Directive that "*an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element*".[173] One of the most prominent cases involving the morality matter concerning DNA modification was a ***Harvard's Oncomouse case 2002***. This case related to so-called transgenic animals problem when genetic material from one living organism is transposed to another living organism into its DNA. DNA is a well-known biological sequence as deoxyribonucleic acid which encodes genetic information. It constitutes the biggest part of a genome ("an organism's complete set of DNA, including all of its genes. Each genome contains all of the information

[171] Ibid.
[172] Oliver, Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (Routledge, New York, 2016), p.14-15
[173] Directive 98/44 EC on the legal protection of biotechnological inventions. Official Journal of the European Communities. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML

needed to build and maintain that organism")[174] of a living organism. In simple words, DNA is a heritable biological material almost for all living organisms.[175] In particular, manipulations with animals' genes and inserting alien DNA into a host organism has become a very important step in science in order to develop new medicines, make animals more resistant to various diseases and even in food quality improvement.[176] Scientists from the Harvard Medical School in 1980s created a so-called *oncomouse* – a mouse which contained an oncogene and was highly susceptible to cancer tumors; subsequently, scientists searched for patent protection of their invention in the USA as well as in many other countries.[177] The Claim 1 contained the following: "*A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising introducing an activated oncogene sequence into a non-human mammalian animal at a stage no later than the 8-cell stage*".[178] The case itself has raised several essential questions for the further animal patenting, for example: should patents be granted at all to animals or their varieties, particularly, to mammals and how should the moral side of this be evaluated in respect of separate questions (suffering of an animal under the clinical trial)?[179] The patent application was refused by the Examining Division in the decision OJ EPO 1989. The Board admitted that, "*The genetic manipulation of mammalian animals is undeniably problematical in various respects, particularly where activated oncogenes are inserted to make an animal abnormally sensitive to carcinogenic substances and stimuli and consequently prone to develop tumours, **which necessarily cause suffering**. There is also a danger that genetically manipulated animals, if released into the environment, might entail unforeseeable and irreversible adverse effects*".[180] EPO decided that the oncomouse definitely brings a "***substantial medical benefit and outweights moral concerns about suffering caused to the animal***".[181] This decision was made on the ground that, "*The decision as to whether or not Article 53(a) EPC is a bar to patenting the present invention would seem to depend mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other*."[182]

Another case where the subject matter was also a mouse is called ***Upjohn case 1992***. This pharmaceutical company created a mouse which contained a gene causing an animal to lose its

[174] NIH, "What is a Genome?"2019, https://ghr.nlm.nih.gov/primer/hgp/genome
[175] Ibid. "What is DNA?"
[176] "Bioethics and Patent Law: Case of the Oncomouse", WIPO, accessed 2 April 2019, https://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html
[177] Ibid.
[178] T0019/90 (Onco-Mouse) of 3.10.1990, Law&Practice, EPO, https://www.epo.org/law-practice/case-law-appeals/recent/t900019ep1.html
[179] Ibid.
[180] Ibid.
[181] Ibid.
[182] Ibid.

hair.[183] In this situation EPO as well as in Oncomouse case evaluated possible positive outcomes for society and negative effects on the animal and reached a conclusion that the invention contains unpatentable subject-matter because negative side outweighed positive results.[184]

Polyploid Oyster was a case in the United States triggered by application of the Coast Oyster Company to obtain a patent protection for the "triploid-sterile Pacific oyster".[185] The idea was to extend the protection for an animal too and claimants proved that the invention contained all necessary conditions as the oyster was sterile and thus their weight was relatively small what made them eatable all the year.[186] An Examiner rejected the claim on the ground that the the subject-matter was naturally occurring but the Board of Appeals reversed the decision. The latter referred to the Chakrabarty case and stated that,

> The Supreme Court made it clear in its decision in *Diamond* v. *Chakrabarty*, supra, that Section 101 includes man-made life forms. The issue, in our view, in determining whether the claimed subject matter is patentable under Section 101 is simply whether that subject matter is made by man. If the claimed subject matter occurs naturally, it is not patentable subject matter under Section 101. The fact, as urged by the examiner, that the oysters produced by the claimed method are "controlled by the laws of nature" does not address the issue of whether the subject matter is a nonnaturally occurring manufacture or composition of matter. **The examiner has presented no evidence that the claimed polyploid oysters occur naturally without the intervention of man, nor has the examiner urged that polyploid oysters occur naturally**.[187]

Mice are not the only mammals which were affected by human's experiments in genetic modifications. ***Dolly sheep*** is a perfect example. She is a famous sheep that was cloned from a cell. Appeared 20 years ago, Dolly has become almost one of the scandalous creations in biotechnology.[188] Researches from Scotland obtained a cloned sheep from a special process called "somatic cell nuclear transfer" (SCNT).[189] Somatic cell nuclear transfer is a technique which allows to improve reproductive features in human organism as well as to "expand the

[183] "Bioethics and Patent Law: Case of the Oncomouse", WIPO, accessed 2 April 2019, https://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html
[184] Ibid.
[185] Matthew Rimmer, *Intellectual Property and Biotechnology (UK: Edward Elgar MPG Books Ltd, Bodmin, Cornwall, 2008)*, p. 84
[186] Ibid.
[187] *Ex Parte Allen* 2 USPQ 2d, p. 1425, 2 (1987). Ibid.
[188] David Tod, "Dolly the sheep's scientific and ethical legacy", Rathbone Brothers PLC, 2019, https://www.rathbones.com/knowledge-and-insight/woolly-thinking-dolly-sheeps-scientific-and-ethical-legacy
[189] Russell, Blackford, "Dolly the Sheep and the human cloning debate – twenty years later", The Conversation, 2019, https://theconversation.com/dolly-the-sheep-and-the-human-cloning-debate-twenty-years-later-63712

reproductive techniques in mammals" overall.[190] Actually, this proved that a living creature can easily develop from a part of a living organism (e.g. from a gland cell as it was in case with the sheep).[191] Of course, there were a lot of debates about the positive and negative outcomes of the birth of a cloned animal. For some reasons Dolly cannot be considered as a full clone but rather as a *sui generis* (the sheep appeared from combining two cells one of which was sexual and not from combination of cells through asexual way).[192] But despite this fact, the animal was highlighted in scientific and usual press that it was a true clone because: *she was born not in a natural reproductive way by virtue of combination male and female cells; the cell was itself modified to make from an adult cell a stem one*.[193] The problem of cloning of animals has incurred a common fear that human cloning is an inevitable horror of the future. However, has it become true? Nowadays it is still prescribed by law that cloning of human beings is prohibited. It can be suggested that Dolly made a great impact on legal regulation and forced a lot of states to ban cloning, particularly, human beings. This sheep was a start point after which a lot of various companies proposed to clone animals that was quite expensive (e.g. to clone polo horses cost even more than $120.000).[194]

Interestingly, in 1989 Kastenmeier introduced a ***Transgenic Animal Patent Reform Act*** which allowed farmers to reproduce, use and sale patented animals and their offspings.[195] However, the Bill was not passed as Kastenmeier lost his position in the elections in 1990s and the draft of the ambiguous act was never introduced into the law again.[196]

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[190] Fermin Roland Schramm, „The Dolly case, the Polly drug, and the morality of human cloning", Cad. Saúde Pública, Rio de Janeiro, 15(Sup. 1):51-64, 1999, p. 53, https://www.researchgate.net/publication/13200659_The_Dolly_case_the_Polly_drug_and_the_morality_of_human_cloning

[191] David Tod, "Dolly the sheep's scientific and ethical legacy", Rathbone Brothers PLC, 2019, https://www.rathbones.com/knowledge-and-insight/woolly-thinking-dolly-sheeps-scientific-and-ethical-legacy

[192] Fermin Roland Schramm, „The Dolly case, the Polly drug, and the morality of human cloning", Cad. Saúde Pública, Rio de Janeiro, 15(Sup. 1):51-64, 1999, p. 53, https://www.researchgate.net/publication/13200659_The_Dolly_case_the_Polly_drug_and_the_morality_of_human_cloning

[193] Ibid. P. 53

[194] Haley, Cohen, "How champion-pony clones have transformed the game polo", The Vanity Fair, 2015 August, https://www.vanityfair.com/news/2015/07/polo-horse-cloning-adolfo-cambiaso
Raj D. Pai & Jason J. Jardine, "The Law and Human Cloning", Knobbe Martens, 2019, https://www.knobbe.com/news/2018/06/law-and-human-cloning

[195] Matthew Rimmer, *Intellectual Property and Biotechnology (UK: Edward Elgar MPG Books Ltd, Bodmin, Cornwall, 2008), p.89*

[196] Ibid.P.89

3.3. THE LONG-STANDING DILEMMA OF HUMAN CLONING

3.2.1. GENERAL OVERVIEW

Cloning. For some this word already sounds scary and unpleasant. It triggers the weirdest emotions and of course – total rejection. But the cloning dilemma is not new at all. It appeared long ago in the middle 1960s when for the first time human cloning was offered as a "*scientific solution to preserving the endangered species of humanity*".[197] On the top of that, after a Dolly sheep case took place, as it has been already mentioned, it became obvious for the society that something should be done in order to prevent such a fixed idea of cloning and, possibly, humans. Definitely, cloning of plants and animals has nothing to do with human beings and, thus, the first are not prohibited by law. But still, there were a lot of opponents to patenting any high organized living organism. For example, one American "Anti-Vivisection Society" organized a special campaign against patenting animals. The ground for that was explained in the next way: "*Just like toasters, clocks, and other inanimate object inventions, animals are being patented in the United States. Private companies, universities, and individual "bioentrepreneurs", have been granted over 470 patents on animals such as monkeys, mice, dogs, cats, sheep, and chimpanzees […] It is our position that it is an inappropriate use of the patent system and unethical to issue patents for sentient beings*".[198] The main idea of the society was to protect high life forms from evil experimentations when the borderline of what can be borne by an animal in respect of pain is extremely exaggerated.[199] To my mind, the question whether the high life forms can be considered as inventions and, thus, patented is rather vague. It should be definitely differentiated between what one calls an invention per se, that is the center of interest for IP law, with how this invention is obtained. IP law does not question this. If it is considered as such – no more deliberations are needed. If there are doubts about technical character, a Patent Office will examine and decide whether there is an invention at all. The interest for the science and IP law – is a life form which constitutes an invention, i.e. it is technical by nature but not the moral debate how this invention was made. Of course, society cannot close its eyes to how animals might be exploited during various experimentations. Various NGOs are essentially needed not to allow science to cross the borderline but I would rather agree with the *thought that biotechnology deals purely with technical side* – not with the morality. Unfortunately, ethics and morality are very indefinite notions that's why restrictions which may be imposed by them can entail contrary

[197] Ibid.P.89
[198] Stop Animal Patents, http://www.stopanimalpatents.org/
Matthew Rimmer, *Intellectual Property and Biotechnology (UK: Edward Elgar MPG Books Ltd, Bodmin, Cornwall, 2008), p.83*
[199] Ibid. P. 83

– bad effects and demolish technical research and development. The main concern from the opponent's side relates to a common unease that soon everything will become a property and even a life. That animals are close to humans and, thus, the next step will be owing human's life. But, again, one should ask himself a question: is not it that sometimes IP issues go too far and reach a some extent of rave? The fact is that except of emotions and bare allegations which can be perceived from opponent's side, it is almost impossible to find any backed up comment why humans should be the next.

In 2005 United Nations adopted a document named *Declaration on Human Cloning* with the only aim to prohibit this issue. It was stated that, "*All forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life should be prohibited*".[200] UNESCO prohibited cloning of humans in the Universal Declaration on the Human Genome and Human Rights 1997, the World's Health Organization, Council of Europe in the Additional Protocol to the Convention on Human rights and Biomedicine, on the Prohibition of Cloning Human Beings and Charter of Fundamental Human Rights 2012 issued by the EU as well.[201]

The USA took such a position that Federal law namely concentrated on investing and funding and only referred to cloning indirectly.[202] The first Bill prohibiting cloning was adopted in 14th Congress, which stated that, "*It would be unlawful for any public or private entity to perform human cloning and included fines up to 1,000,000 dollars*". Within the 114th Congress human cloning was prohibited. However, this prohibition only relates to human cloning for reproduction and research but does not ban the usage of "*nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants or animals other than humans*".[203] The Bill defined human cloning as "*asexual reproduction, accomplished by introducing the nuclear material of a human somatic cell into a fertilized or unfertilized oocyte whose nucleus has been removed or inactivated to produce a living organism (at any stage of development) with a human or predominantly human genetic constitution*."[204]

[200] Adele Langlois, "The global governance of human cloning", Palgrave Commun. 2017 Mar 21; 3: 17019. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5378293/
[201] Ibid.
[202] "The Law and Human Cloning", Knobbe Martens, 2019, https://www.knobbe.com/news/2018/06/law-and-human-cloning
[203] Human Cloning Prohibition Act of 2105 (Bill), Congress.gov,https://www.congress.gov/bill/114th-congress/house-bill/3498/all-info
[204] Human Clonin Prohibition Act of 2015 (Bill), Congress.gov, https://www.congress.gov/bill/114th-congress/house-bill/3498/text

3.2.1. PROS AND CONS OF HUMAN CLONING

Notwithstanding the fact that generally human cloning is not accepted as a positive and necessary scientific performance, and despite the fact that it also contradicts all ethical and moral settings, I would like to analyze pros and cons of such activity. So, what are the good reasons to accept cloning of human beings, if there are any? First of all, "cloning" as notion better to envisage from different perspectives. The first one is the *cloning itself which is conducted by virtue of asexual combination of cells* (normally used in plant breeding) that makes live forms genetically the same but not always because of genetic mutation; the second concerns *cloning by usage of embryos*: dividing an embryo cell, resulting from combination of male and female reproductive cells; the third one was already mentioned in Dolly case where the sheep was produced by a *SCNT process*: a clone has the same DNA as the donor.[205] All these three situations can be considered from the point of view of morality. The first case unlikely will trigger any doubts because asexual reproduction is widely used among plants, no moral restrictions can be imposed. The second and the third cases can be applicable to human clones, that is why some moral restriction can be imposed here. In "The Dolly case, The Polly Drug and the Morality of Human Cloning" the author differentiates between embryo cell division and SCNT tool. He explains that there is a "vertical" genetic information copying in SCNT where the new born clone can be identified by donor DNA whereas in embryo case there is a "horizontal" genetic information copying and one can only access what approximately a new born cell might get by virtue of mixing male and female gametes[206][207]. The author also makes a conclusion that based on this explanation, moral restriction can be only implicated in the case of SCNT cloning because in this case two organisms are identical, that is what understood by most of the people under cloning.[208] SCNT technique has two types: a so-called research cloning and reproductive one. *Research cloning* means that it is conducted to get embryo stem cells whereas *reproductive cloning* is used simply to obtain cloned animals.[209] But, in essence, these two types are not different, they only differ in their purposes of usage which derive from the names of techniques.

[205] Fermin Roland Schramm, „The Dolly case, the Polly drug, and the morality of human cloning", Cad. Saúde Pública, Rio de Janeiro, 15(Sup. 1):51-64, 1999, p. 58-59, https://www.researchgate.net/publication/13200659_The_Dolly_case_the_Polly_drug_and_the_morality_of_human_cloning

[206] Gamete – a reproductive cell.

[207] Fermin Roland Schramm, „The Dolly case, the Polly drug, and the morality of human cloning", Cad. Saúde Pública, Rio de Janeiro, 15(Sup. 1):51-64, 1999, p.59, https://www.researchgate.net/publication/13200659_The_Dolly_case_the_Polly_drug_and_the_morality_of_human_cloning

[208] Ibid.P.59

[209] Marin, Gillis & Inmaculada de Melo-Martin,"The ethics of human cloning". In *The SAGE Encyclopedia of Stem Cell Research.* SAGE Publications, Inc 2015, USA. P.3, https://www.researchgate.net/publication/297408833_The_Ethics_of_Human_Cloning

I agree that cloning should be embraced from two different sides: from *biological* and *personal* as well.[210] Biological part refers strictly to what a clone obtains from its donor – namely, the same physical characteristics, – becomes a copy of its parent. However, personal – is the part which cannot be observed in a clone, i.e. life experience, features of character, behavior, emotions. When assessing morality side of cloning, I would like to emphasize on outcomes which such activity brings to science and society. To my mind, it is not appropriate to assess this matter from the deontological point of view: what is good and what is bad.[211] Namely, in research cloning scientists widely used **embryo cells**. As the main resource still remain fertility clinics,[212] however, they are not so effective in trials as natural embryo cells which are more resistant to negative influence and is better accepted by humans in treatments.[213] Opponents of using embryo in researches state that embryos are already humans, that is why, demolishing an embryo is considered the same as a murder.[214] Although embryo is not a human yet and does not possess all necessary neither physical nor psychological traits, it is still able to develop into a full of value human.[215] I consider the "murder argument" to be of more deontological approach[216] than of purely scientific because embryo indeed can be developed into a human but before the birth it is still a biological living form which possesses no psychological traits. Thus, eventually, embryo cannot fully owe a moral status.[217] There is also another idea of what is an embryo itself. Proponents of this theory allege that embryo is not a human but also not a simple cell that is why it should be granted a separate status and should not be used in research cloning.[218] Another not less important ethical issue is the *usage of women donors* for embryo manipulations. The risks are quite high: women have to take hormone pills, injections and use other medical tools to stimulate the growth of artificial ovulation and at the same time to cease the normal one.[219] The drug which is normally used is called leuprolide acetate[220] can cause a lot of problems to a

[210] Fermin Roland Schramm, „The Dolly case, the Polly drug, and the morality of human cloning", Cad. Saúde Pública, Rio de Janeiro, 15(Sup. 1):51-64, 1999, p.59-60, https://www.researchgate.net/publication/13200659_The_Dolly_case_the_Polly_drug_and_the_morality_of_human_cloning
[211] Ibid.
[212] Fertility clinic – a clinic which helps couples to achieve pregnancy which cannot do so in natural way by virtue of health or genetic problems.
[213] Marin, Gillis & Inmaculada de Melo-Martin,"The ethics of human cloning". In *The SAGE Encyclopedia of Stem Cell Research.* SAGE Publications, Inc 2015, USA. P.3, https://www.researchgate.net/publication/297408833_The_Ethics_of_Human_Cloning
[214] Ibid. P.4
[215] Ibid. P.4
[216] Analyzing the matter from the point of view "good" or "bad".
[217] Marin, Gillis & Inmaculada de Melo-Martin,"The ethics of human cloning". In *The SAGE Encyclopedia of Stem Cell Research.* SAGE Publications, Inc 2015, USA. P.5, https://www.researchgate.net/publication/297408833_The_Ethics_of_Human_Cloning
[218] Ibid. P.5
[219] Ibid.P.5
[220] A hormone which inhibits the level of estrogen in woman's organism. Used to cure cancer of reproductive organs.

donor's health such as headaches, vazodilations[221], infections, increase cancer susceptibility, depression, chest pain, anxiety, insomnia, dizziness and even death.[222] One of the most negative effects is an Ovarian Hyperstimulation Syndrome (OHSS). This syndrome mostly leads to the death, damages kidneys and causes a lot of other problems.[223] The moral problem is not only represented by the suffering and risks which donors bring on themselves but also the matter of exploitation mostly the part of humans who is on a low socio-economical level.[224]

Art. 6 of the Biotechnology Directive in paragraph 2 subparagraph c) states that "*uses of human embryos for industrial or commercial purposes shall be considered unpatentable*".[225] Industrial and commercial purposes can be understood as the forms of exchange in order to obtain some kind of values (e.g. monetary) involving some technical interference.[226] Thus, only *therapeutic and diagnostic objectives* can be considered as acceptable in usage of human embryos.[227] European law does not give a definite understanding of what is a human embryo. Is it an organism, a cell or an intermediate life form? Generally, there are three main definitions of what constitutes an embryo: it is a human and thus it has a right to live; it is a "heap of the cells", that is why, it should be considered the same way as usual cells; it is not a human but has a potential to be developed into a human personality and, thus, needs a special kind of protection.[228] Some of the national laws designate the notion of human embryo, here some of them: The Embryo Protection Act in Germany in Clause 8 identifies "*an embryo as a fertilized egg cell with the capacity to develop from the moment of the fusion of the nuclei*"[229]; Italian law defines embryo as "*zygote and all subsequent stages of its development until the completion of implantation*"[230]; Romanian law (project) defines an embryo as "*the organic assembly of cells,*

[221] The widening of blood vessels.
[222] Judy, Norsigian, "Egg donation dangers", CRG, 2019, http://www.councilforresponsiblegenetics.org/ViewPage.aspx?pageId=103
[223] Marin, Gillis & Inmaculada de Melo-Martin,"The ethics of human cloning". In *The SAGE Encyclopedia of Stem Cell Research.* SAGE Publications, Inc 2015, USA. P.6
[224] Ibid. P.6
[225] Directive 98/44 EC on the legal protection of biotechnological inventions. Official Journal of the European Communities. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML
[226]Andrea, Radonjanin, "Patentabiliy of Biotechnology: Does Article 6 of the Biotech Directive introduce a single European concept of morality in patent law?", Evropski Pravnik 2007,https://www.academia.edu/8109126/PATENTABILITY_OF_BIOTECHNOLOGY_Does_Article_6_of_the_Biotech_Directive_introduce_a_single_European_concept_of_morality_in_patent_law
[227] Directive 98/44 EC on the legal protection of biotechnological inventions. Official Journal of the European Communities. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML
[228] MARIA ALUAŞ, CLAUDIA DIANA GHERMAN, CRISTIANA IULIA DUMITRESCU, "Is the human embryo legally defined and protected?", Rom J Morphol Embryol 2017, 58(2):695–700, http://www.rjme.ro/RJME/resources/files/580217695700.pdf
[229] Betta Bock von Wülfingen, "Contsted change: how Germany came to allow PGD?", NCBI, accessed 2019 April 4, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5952673/
[230]Andrea, Radonjanin, "Patentabiliy of Biotechnology: Does Article 6 of the Biotech Directive introduce a single European concept of morality in patent law?", Evropski Pravnik 2007,https://www.academia.edu/8109126/PATENTABILITY_OF_BIOTECHNOLOGY_Does_Article_6_of_the_Biotech_Directive_introduce_a_single_European_concept_of_morality_in_patent_law

which, by development, may give a birth to a human being"[231]. The European Court of Justice in 2011 ruled in the case called Oliver Brüstle v. Greenpeace that, "*Any human ovum after fertilization, any non-fertilized human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilized human ovum whose division and further development have been stimulated by parthenogenesis*[232] *constitute a "human embryo" within the meaning of art. 6(2)(c) of the Directive.*"[233] So, for states which have designated what is a human embryo will be easy to identify which kind of embryos are susceptible to commercial or industrial applicability and subsequently abandon them from patentability.[234] However, in some states the meaning of embryo is differentiated from embryo stem cell and, thus, the latter does not fall under the excluded scope of paragraph 2 art. 6 Biotechnology Directive.[235] Of course, the wording of art. 6 of the Directive gives a loophole to obtain a patent to embryonic stem cells because they do not constitute an entire organism after the extraction as they derive from the "*undifferentiated inner mass cells of human embryo*".[236] Despite this fact, I would not enlarge the scope of the provision to include embryonic stem cells because they constitute an essential tool in biotechnological science.

The main **advantage** of human cloning is that it definitely will help to treat genetic diseases which cannot be cured now, e.g. orphan diseases[237]. Some argue that it is a good way to cure different injuries and traumas due to the replacement of damaged cells by new ones. It is widely known that a lot of people die each year waiting for a donor organ or tissue in order to survive incurable diseases. The only way to struggle with this problem – is to interfere in damaged genes and correct them (nowadays CRISPR Cas9[238] system is already applied to somatic cells[239]). Another positive effect of human cloning is that it definitely will change the science on a whole and avoid infertility because then future parents will be able even to decide

[231] MARIA ALUAȘ, CLAUDIA DIANA GHERMAN, CRISTIANA IULIA DUMITRESCU, "Is the human embryo legally defined and protected?", Rom J Morphol Embryol 2017, 58(2):695–700, http://www.rjme.ro/RJME/resources/files/580217695700.pdf
[232] Asexual form of fertilization.
[233] Judgment of the Court (Grand Chamber), 18 October 2011,
MARIA ALUAȘ, CLAUDIA DIANA GHERMAN, CRISTIANA IULIA DUMITRESCU, "Is the human embryo legally defined and protected?", Rom J Morphol Embryol 2017, 58(2):695–700, http://www.rjme.ro/RJME/resources/files/580217695700.pdf
[234]Andrea, Radonjanin, "Patentabiliy of Biotechnology: Does Article 6 of the Biotech Directive introduce a single European concept of morality in patent law?", Evropski Pravnik 2007,https://www.academia.edu/8109126/PATENTABILITY_OF_BIOTECHNOLOGY_Does_Article_6_of_the_Biotech_Directive_introduce_a_single_European_concept_of_morality_in_patent_law
[235] Ibid.
[236] Wikipedia, the free encyclopedia, "Emryonic stem cell", ScienceDaily, 2019, https://www.sciencedaily.com/terms/embryonic_stem_cell.htm
[237] Orphan disease – a rare disease. It can appear in embryo stage as well as at early age, a big part of orphan diseases is connected to genetic problems. Affects a small percentage of people worldwide.
[238] CRISPR Cas9 technology – is a so-called gene editing. The system works as following: a protein Cas9 interfere into a damaged DNA part and replaces it with "good" molecules.
[239] Somatic cell – any other cell but not a reproductive one.

the sex, color of eyes and hair of their kids.[240] To my mind, cloning will definitely bring a lot of positive inputs into medical cure and scientific development. I agree that nowadays a lot of people suffer from illnesses which are impossible to deal with or hard to live with and, thus, they need another type of treatment, a new one, on genetic level which medicine is not able to provide (at least now). Moreover, the mankind is one step closer to this after a CRISPR system was developed, however, even this "careful" type of genetic editing is accepted with a big skepticism. So, when do the **morality issues** arise? First of all, when interfering in human's genome. Human's body is sacred and nobody can have an ownership on it except of the individual who physically embodied in it. Any manipulations with the genome make it doubtful who can own the life. A person himself, a scientist or kid's parents when deciding who will born? Secondly, when talking about cloning, there are always two organisms: a donor and a clone. Normally, a question can arise whether it is fair against the donor to use its genetic material to create a clone. Indeed, there are various levels of morality here and they depend on which activity is done. For example, to create a clone to save somebody's life (due to donation of a tissue or organ); or to clone an embryo to "expand woman's procreative autonomy"[241]? Or to create an individual with expanded possibilities as physical endurance? Of course, to create a clone to save other's life is more than a generous idea and at first sight has nothing to do with moral objections, but, in reality, why a clone should suffer from saving somebody – is still a question. To my mind, it will be unfair to the one who should give something from himself without a proper consent. Because it is correct that nobody is forced to donate his part if he does not want to do so as it is a pure autonomy of an individual to decide on its body.[242] Embryo manipulations in technology are prohibited by many laws all over the world. So, the answer to the question about ethics and morality is quite straightforward here. But at the same time a lot of countries accept assistive reproduction technology[243] and the morality issue is not raised at all. But of course, these matters are alike whereas not the same and it should be taken into account too. Another issue at stake – when a clone can be used as an improved personality with specific physical traits. Personally, for me this case is not crystal clear. For some reasons it is obvious that improved genetically, humans can resist a lot of diseases and environmental problems not only by virtue of natural

[240] Crystal, Ayres, „16 important pros and cons of human cloning", GreenGarage, 2019, https://greengarageblog.org/16-important-pros-and-cons-of-cloning-humans
[241] Fermin Roland Schramm, „The Dolly case, the Polly drug, and the morality of human cloning", Cad. Saúde Pública, Rio de Janeiro, 15(Sup. 1):51-64, 1999, p.60, https://www.researchgate.net/publication/13200659_The_Dolly_case_the_Polly_drug_and_the_morality_of_human_cloning
[242] Ibid. P.60
[243] Technology which is used in case of impossibility to being fertilized by virtue of applying various medical techniques.

selection.[244] For opponents of biotechnology and especially cloning that would be directly considered as "playing with God". Interference into natural phenomena is unacceptable and, thus unpatentable per se. But I do not agree with this allegation because inventions connected to DNA are patentable (law and cases prove that). Despite the fact that in the case with DNA scientists use it isolated from the natural environment and subsequently purified, does not remove its true origin. The same is with cloning. Clones do not appear themselves in nature, for that we need human interference and, thus, technical input.

The question that must be also covered is not only the harm donors can experience but also harm which clones might have too. Of course, cloning is undoubtedly a step forward but it still remains a technical process which can also give failures. For example, Dolly the sheep was a successful result only after 277 unsuccessful tries to obtain an animal with specific traits.[245] This simply means that all previous clones obtained disorders and, probably, died. It is impossible in human cloning taking into account that the human's life is considered to be the highest value in all democratic nations.

Personally, I perceive human cloning as a positive step to struggle against various diseases, especially, on genetic level. On the top of that, it can bring resilience towards global world changes which can influence mankind's health and development. However, it is very important for scientists to identify the safest way to use cloning tools in order to significantly minimize the possibility of an error.

3.3. GENOME EDITING: ANY MORAL RESTRICTIONS?

Previously, in this work, I have already mentioned the topic of genome editing, more precisely, the system CRISPR Cas9 used in it. So, what is *genome editing* and what is the difference between it and *genetic modification*? According to the U.S. National Library of Medicine, genome editing is considered as a process of altering DNA in different variations such as: deleting its parts, adding new or just changing them.[246] The methods of DNA editing can be different, everything depends on which kind of sequence manipulation is used. Gene editing is indeed a new and quite perspective technology which can help to "correct" a genome of a living

[244] Fermin Roland Schramm, „The Dolly case, the Polly drug, and the morality of human cloning", Cad. Saúde Pública, Rio de Janeiro, 15(Sup. 1):51-64, 1999, p.60-61, https://www.researchgate.net/publication/13200659_The_Dolly_case_the_Polly_drug_and_the_morality_of_human_cloning

[245] Marin, Gillis & Inmaculada de Melo-Martin,"The ethics of human cloning". In *The SAGE Encyclopedia of Stem Cell Research.* SAGE Publications, Inc 2015, USA. P.9, https://www.researchgate.net/publication/297408833_The_Ethics_of_Human_Cloning

[246], "What are genome editing and CRISPR-Cas9 ?", NIH, accessed 2019 April 8, https://ghr.nlm.nih.gov/primer/genomicresearch/genomeediting

organism that is mutated, ill or has any other drawbacks.[247] The main idea underlying the DNA editing tool is that only the targeted part of genome can be corrected, thus, namely, struggling with the genetic illnesses.[248] I would like to pay attention to one of the newest systems of gene editing which is called CRISPR[249] and its associated protein Cas9. CRISPR Cas9 tool derived from a bacteria editing DNA system. The scheme is quite simple: Cas9, which is a protein[250], plays a role of the scissors and cuts at a particular place of DNA sequence which must undergo changing; gRNA[251] helps Cas9 to find the right part of DNA which must be altered (actually, it plays the role of a guide and ensures that only the desired part will be changed – not any other "by mistake or by accident"); at the end after the part of DNA is cut, a cell gets a signal that a particular part is damaged and should be urgently fixed (Annex 1).[252]

Genome editing cannot be considered the same as genetic modification. The latter refers to modification of a gene itself, by virtue of transferring genes from one living organism to another (it can involve cloning DNA, combining cells, inserting alien genes into a host cell etc).[253] The main aim of genetic modification is to make a host organism with newly inserted genes more resistant to some inefficiencies of environment or various possible diseases. Science actively develops primarily DNA modification in crops and animals in order to make them resistant to viruses, yeasts or to gain some aesthetic traits. Neither genetic modification nor gene editing are mentioned in the excluded scope in Biotechnology Directive as well as EPC. However, par. 2 art. 6 of Biotechnology Directive mentions that inventions shall be considered unpatentable: b) processes for modifying the germ line genetic identity of human beings, c) uses of human embryos for industrial or commercial purposes and d) processes of 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.[254] Paragraphs a) and d) mention modifying genetic lines of humans and animals as non-patentable inventions but gene editing is a tool wich corrects but not modifies the DNA itself. It should be also mentioned that there is a difference between the *germline editing* and *somatic editing*. The attention was drawn into this issue not so long ago: when the Chinese researcher He Jiankui has

[247]Bethesa, Maryland, "Genome Editing Trchnologies: Defining a Path to Clinic", Moleular Therapy, vol. 23 no. 5 May 2015, p. 796, https://www.cell.com/action/showPdf?pii=S1525-0016%2816%2930103-4
[248] Ibid., p. 796
[249] Clustered regularly interspaced short palindromic repeats.
[250] Also an enzyme.
[251] Guiding Ribonucleic acid.
[252] "What is CRISPR-Cas9?", Yourgenome.org, accessed 2019 April 8, https://www.yourgenome.org/facts/what-is-crispr-cas9
[253] P.Byrne, "Genetically Modified (GM) Crops: Techniques and Applications", Colorado State University, soil and crop sciences. 8/2014, https://extension.colostate.edu/docs/pubs/crops/00710.pdf
[254] Directive 98/44 EC on the legal protection of biotechnological inventions. Official Journal of the European Communities. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML

used human embryo in gene editing experiments.[255] The researcher claimed that he conducted a germline editing that is totally not the same as a somatic cell editing.[256] *Somatic therapy* is used to edit human's DNA in order to get rid of various genetic mutations whereas germline editing is used namely to influence all the cells, including also reproductive ones and, thus, affecting future generations' DNA sequences (Annex 2).[257] Of course, scientists and society wonder what are the potential risks of these tools and whether the advantages of using CRISPR indeed outweigh risks to humans and environment in total. Feng Zhang, a famous scientist known for his leadership in CRISPR systems replied to Jiankui's wish to provide moratorium on inserting modified embryos into a woman: "*The moratorium is a pause. Society needs to figure out if we all want to do this, if this is good for society, and that takes time. If we do, we need to have guidelines first so that the people who do this work can proceed in a responsible way, with the right oversight and quality controls*."[258] As in moral and ethical questions of using animals in clinical trials while developing a new invention, the same is noticeable in the situation of genome editing. It is true that society cannot adequately decide itself what outweighs: risks to health or a possibility of live saving. The main concern is that there will be always a part calling for gene therapy because it can indeed save lives, increase comfort of living and cure many genetic diseases but at the same time nobody knows what stands behind reaching such achievements in biotechnology and medicine: hazardous clinical trials, possibly deaths. Where is a borderline, the balance between technology development and danger to society? I cannot say precisely whether moratorium is a good or bad idea. The question about using *modified embryos* is doubtful per se. And as I have already emphasized, the society cannot decide itself if it is needed or not. Society is a collective notion, it names *everybody* and *nobody* at the same time. Who will be responsible for the decision made by it? It is almost impossible to answer that is why I stand for an idea that this is a prime task of legislators, Patent Offices and of course judicial bodies to decide on this matter. It is still not know how gene editing will influence the future development of further generations. Professor Glenn Cohen drew attention to the problem of legal and biotechnological correlation. He admitted that in order to speak about decent legal regulation in the sphere of gene editing techniques everybody should be brought together. And "*It is very hard to deal with a transnational problem with national legislation […]*"[259], however possible to regulate all these issues on international scale.

[255] Mary Todd Bergman, "Perspectives on Gene Editing", The Harvard Gazette, 2019 January 9, https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/
[256] Ibid.
[257] Ibid.
[258] Ibid.
[259] Ibid.

4. MORALITY AND BIOPRINTING

4.1. TRANSPLANTATION TOURISM AND ORGAN PRINTING

In this chapter I would like to cover such challenging problem as bioprinting, in other words – 3-D printing of organs. It might seem that 3-D printing is quite a new technology used in its various fields, however, this tool was created long ago, in 19th century and already in 1999 the first printed human organ was transplanted.[260] It is widely known that there is a catastrophic shortage of donor organs in the world. Millions of people die every year while waiting in the list for their turn to get a needed organ. According to the USA OPTN, the most needed organs are kidneys – 94,913 and liver – 13, 317 on waiting list as of 31 March 2019.[261] Among others are pancreas, heart, lungs, intestine and all in all there are 113,728 organs in need.[262] According to the statistics of OPTN, in January-February 2019 only 6,100 operations were performed and that using organs of deceased ones – 4,895.[263] In Europe in 2015 waiting lists of donor organs were represented by more than 143 000 persons and on average 18 people on the waiting list die every single day.[264] The problem of organ shortage as well as of some state's policy (e.g. an opt-in system by virtue of which people should sign for donation after their death voluntarily in order to make their organ being extracted after their death) make it difficult for patients in waiting lists to obtain organs. Moreover, this creates a favorable atmosphere for trafficking in humans and their organs. For poorest to sell their organ is the only way to survive, for rich – it is a way to get a second chance life. Many people are involved in so-called transplant tourism (TT). TT is a part of medical tourism which describe a situation when people travel abroad in order to obtain a needed organ. TT can take various forms, and very often rather difficult schemes (Annex 3). TT is also a highly debatable question regarding ethical aspects. The key points which demonstrate position against are: abuse of minorities and poor which is a form of taking advantage; corruption on a high scale in which can be involved different parties, e.g. hospitals. Corruption creates a view that humans are property, in particular, it undermies human dignity: "*Dehumanize society by viewing human beings and their parts as mere commodities*".[265] Moreover, there is a

[260] Dana Goldberg, "History of 3-D Printing: It's Older Than You are (That is, if You're Under 30)", Redshift Autodesk, 2019, https://www.autodesk.com/redshift/history-of-3d-printing/
[261] Organ Procurement and Transplantation Network, U.S. Department of Health & Human Services, 2019, https://optn.transplant.hrsa.gov/data/
[262] Ibid.
[263] Ibid.
[264] The European Day for Organ Donation and Transplantation, Council of Europe, 1 Newsletter Transplant 2016, published September 2016, https://www.edqm.eu/sites/default/files/factsheet_organ_donation_eodd_2017.pdf
[265] I.Glenn Cohen, "Transplant Tourism: The Ethics and Regulation of International Markets for Organs", global health and the law symposium, 2013, https://poseidon01.ssrn.com/delivery.php?ID=669114026017099019119067108068098117049076007008012001100

widespread thought that allowing to sale organs will create a situation when shuch organs will be reduced in amount because of general altruistic aim of donation.[266] Abuse of human dignity – is central ethical aspect in TT. Human dignity is a notion which refers to all humans as the highest social value, their respect and appreciation based on the fact that they are humans.[267] TT is regarded namely as an activity which undermines humans and their value because latter are misused in most cases while selling their organs. The problem is that normally donors sell organs because of extreme poverty in which they live. Africa, India, Iran, Mexico – all these countries are on the list of high rate distribution of organs worldwide.[268] But one can say that there is always a consent between parties. Seller and buyer act voluntarily, nobody forces them to sell or to buy and being involved in illegal transplant tourism. However, there are also remarks. First of all, consent can take various forms, taking into account that seller is not always an organ possessor. Thus, it is obvious that the organ might be or stolen or sold by virtue of focing donor to do that. There are many illicit forms of conducting trafficking in organs but I consider that there is no any kind of free consent in TT. Even if donors themelves decide to sell their organ – they do it not because of altruism, they do it because they simply in need. So, that is a form of exploitation when buyers take an advantage of those who are desparate, despite the fact that there might be no physical or psychological influence conducted regarding such donors. The ethical aspect is very bright in TT and society should always remind to itself: every time an organ is sold and transplanted illegally, there are less and less organs for patients who are on waiting lists, thus, TT kills both donors (most of them die because of bad treatment and infection) and potential patients who are in urgent need to get an organ legally. Taking into consideration all abovementioned, are there any ways if not to destroy, at least significantly minimize the problem of organ donation all over the world? Yes, there is a way out and the key to this problem is biotechnology, 3-D organ printing. To better understand this technology, I would like to briefly describe how this system works.

3-D printing is in its essence bioprinting which according to Oxford dictionary means "The use of 3D printing technology with materials that incorporate viable living cells, e.g. to produce tissue for reconstructive surgery".[269] Bioprinting as a new rechnology appeared in 1988

310707011806600312402602911301712201102405802401907502407601206400112610401103503301302411108011608602310203507705209201209202500107211500508606711801909612502706609012310107708406809107 2065007&EXT=pdf

[266] Ibid.

[267] "Human Dignity", The Centre of Bioethics & Human Dignity, accessed 2019 April 9, https://cbhd.org/category/issues/human-dignity

[268] "Organ Trafficking: The Unseen Form of Human Trafficking", AML Challenges, Acams Today, 2018, https://www.acamstoday.org/organ-trafficking-the-unseen-form-of-human-trafficking/

[269] Oxford Living Dictionaries, "Bioprinting", Oxford University Press 2019, https://en.oxforddictionaries.com/definition/bioprinting

when Robert J. Klebe found out a method for the "micropositioning of cells".[270] This technique (Annex 4) uses natural material of an organism (e.g. cells) and artificial compositions (in most cases biopolymers) to create so-called bio-links which are grown layer by layer in order to imitate mature tissue at the end and be able to implant it into the organism.[271] Normally, a biopsy of a particular organ is taken from a patient, then the cells are being extracted, subsequently, increased and put on the special scaffold in order to let them grow in a whole tissue.[272] Stem cells are the hope of the bioprinting and medicine because, as it was previously mentioned, they can subsequently develop in any type of cell, so the use of them is quite promising in curing all types of diseases. In bioprinting and various researches conducted in connection with this technology scientists normally use adult stem cells, not embryonic ones because the latter can raise a lot of concerns, i.e. ethical and moral about usage of embryons themselves.[273] On the top of that, stem cells are difficult to increase in number because they have "finite lifespans".[274] Notwithstanding the fact that there are still a lot of issues that should be developed and improved, Patent Offices receive a lot of applications concerning bioprinting. According to the study of Hornick and Rajan, applications in bioprinting have been continuously raising scince 2015 from 700 to 900 up to 2016, moreover the patent growth has been estimated in 36% totally.[275] The leader among other countries is the USA (around 40% of bioprinting companies are established at that area), the other territories – are Europe and Asia.[276] Among famous companies are Organovo which works with designing, creating and trading in human organs and tissues that resemble in almost precise manner the real ones,[277] 3Dynamic Systems which are eager to produce such human parts

[270]Hannes, Karrenbrok, "The Ethical Controversy about 3D Bioprinting"(master thesis, Tilburg Law School, 2018) p.7, http://arno.uvt.nl/show.cgi?fid=144814

[271] Farai Mashambanhaka,"What is 3D-Bioprinting?", 2018, All3DP, https://all3dp.com/2/what-is-3d-bioprinting-simply-explained/

[272] Ibrahim T. Ozbolat & Yin Yu, Bioprinting Toward Organ Fabrication: Challenges and Future Trends, 60 IEEE TRANSACTIONS ON BIOMED. ENGINEERING. 691, 691 (2013). 4. Id. at 692-93, fig.2; see infra Figure 2. Mathew Varkey,"Organ Bioprinting: A Closer Look at Ethics and Policies", 2015, p. 274, https://www.researchgate.net/publication/281639838_Organ_Bioprinting_A_Closer_Look_at_Ethics_and_Policies

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[277]Timo Minsen & Marc Mimler, "Patenting Bioprinting-Technologies in the US and Europe – the 5th Element in the 3rd Dimension", p. 2, http://eprints.bournemouth.ac.uk/29809/3/2%20cg%2031%20mar_Ch%207_Bioprint_Minssen_Mimler%20review%20MMTM%2029032017%20review%20MDM%2031032017.pdf

as bones, muscles and of course skin[278] and many others which deal with printing equipment, research and medical markets all over the world. Without a doubt, bioprinting is a relatively new technology and is still not widespreadly used in surgery and transplantology because of various drawbacks and scientific concerns. However, it is definitely a promising tool for the future science which raise not only purely technical questions but also ethical and legal ones.

4.2. ETHICAL AND LEGAL CONCERNS IN FUTURE OF BIOPRINTING

Without a doubt bioprinting is surrounded by many discussions in terms of its ethical status. From the one side this sphere of biotechnology can boast many other technological and medical fields, increase the level of science on a whole. It is also quite promising in the transplantation of human organs taking into account the overall shortage of the latter in the world. From the other side bioprinting raises a number of moral questions in connection to business, healthcare and even prosperity of future generations.

The first ethical issue related to bioprinting, i.e. organ printing, is its *commercialization*. I have already mentioned the fact that 3-D organ printing is very expensive activity and there are onle a few companies worldwide which do bioprinting and conduct researches in this sphere. Patenting of biotechnology is problematic per se because of costs for R&D and introduction of a new inention into the market, thus 3-D printing is even more difficult to develop and patent because of plenty of challenges it raises: "*The only economic and reasonable way to commercialize organ-printing technology is to systematically employ scalable automated robotic technology and to build an integrated organ biofabrication line. It is not sufficient to develop just one robotic device—a bioprinter…[it] will require the development of series of integrated automated robotic devices, or an organ biofabrication line*".[279] Nowadays 3-D bioprinitng is more considered as a personalized medicine[280] because it still cannot be used on a larger scale, but once it becomes improved and subsequently widespread, it will create a disbalance between people who can afford it and others who cannot.[281] Personally, I agree that even nowadays all biotechnological advancement is affordable almost exclusively to the richest (the newest

[278] Brian Krassenstein, "11 Companies Leading the 3D Bioprinting Space", 3D Print.com, 2015, https://3dprint.com/88792/3d-bioprinting-companies/

[279] Myronov V, Kasyanov V, Markwald PR. Organ Printing: from bioprinter to organ biofabrication line. Curr Opin Biotechnol 2011;22:667-73. Niki Vermeulen, Gill Haddow, Tirion Seymour and others, "3D bioprint me: a socioethical view of bioprinting human organs and tissues", 2017;43:618–624.doi:10.1136/medethics-2015-103347. https://jme.bmj.com/content/medethics/43/9/618.full.pdf

[280] Is a term that describes treatment suitable for a particular patient taking into account his individual medical features and disease which should be treated. However, despite the name of the therapy, it is considered to be advantageous not only to a particular individual but to medicine on a whole.

[281] Mathew Varkey,"Organ Bioprinting: A Closer Look at Ethics and Policies", 2015, p. 287, https://www.researchgate.net/publication/281639838_Organ_Bioprinting_A_Closer_Look_at_Ethics_and_Policies

medicine, kind of therapies and even 3-D organ printing on restricted amount). This of course creates an unfair situation towards all other people who need such treatment but simply cannot imagine collecting the needed amount of even for 1 therapy. This issue is strictly connected to the costs which companies invenst in development of technology and costs then which they pay to get the exclusive rights to inventions. On the top of that, such a monopolization of intellectual property rights will undoubtedly bring up even more disequilibrium in humans value and in a way it will be considered the same as trade in organs. So, what are expectations? Nowadays, it is hard to predict how long it will take to fix the adequate and safe production of 3-D organs. Taking into account the current developments, several years are needed as well as the precise assurance that such organs will be in a high demand, otherwise businesses will have no interest in improving this field taking into consideration how much resources are necessary in order to achieve a needed outcome.

The second ethical aspect in biopring is the *level of safety in healthcare*. Probably, that is the core issue because nothing matter more than human, his life and health. The biggest concern in organ printing is about quality of materials used, which can contain autologous[282], allogenic[283] cells derived from different species.[284] The results of inserting such cells into a human organism are rather lamentable: appearance of undesired hazardaous agents such as bacteria, viruses and ill cells, this all might also lead to a non-acceptance of the organ by an immune system, which will be impossible to suppress by even antibiotics.[285] Eventually, such an organ will be rejected by organism and the human might die from septicemia[286]. Clinical trials are very important in implantation of printed organs, especially the reaction of immune system on an implant because as it is widely known even a ususal implantation of an organ derived from a living donor – human being – can be easily rejected by recipient. That is why, nowadays, 3-D printing of organs for transplantation is a highly risky process which needs more researches in order to be introduced into medicine and be regulated legally.

Biotechnology Directive as well as EPC neither explicitly mention nor prohibit 3-D printing of human organs. However, there might arise a question whether such an activity is against ordre public and morality under both legal documents. Human cloning is strictly prohibited by European patent law, however, it is doubtful if printed organs are considered to be clones. Literally, indeed, they reflect the same biological structure as real ones, and from that point of views they can be regarded as cloned. But I would not agree with this opinion because a

[282] Cells which are extracted and then implanted back and refer to the one individual.
[283] Cells which are taken from the matching donor and implanted into a patient's organism in order to cure a disease.
[284] Mathew Varkey,"Organ Bioprinting: A Closer Look at Ethics and Policies", 2015, p. 287, https://www.researchgate.net/publication/281639838_Organ_Bioprinting_A_Closer_Look_at_Ethics_and_Policies
[285] Ibid. P. 287
[286] Blood poisoning.

cloned organ is not a cloned human being, moreover, material which is taken for creation an organ is naturally occurring but anyway further is technically used, combined with polymer and the whole process is fully conducted by the human operation. Under European legal regulation it will be difficult to use embryonic cells in production of printed organs because it is prohibited by law.

Can it be possible that the organs even created by a human will become a property of inventors, companies, investors? How does it correlate with the fact that human body is sacred and everyone is the host of his own? Indeed patent law does not contemplate about philosophical issues, and it should not do it. A 3-D printed organ is just a technical solution, an advancement in technology and a step forward in medical treatment. Commercialization of printed organs should not in any way be equalized with TT and should take the separate place in patent regulation.

US patent law as well as EU law in principle allows to obtain a patent on a bioprtinted organ at least nowadays, however, there is a big question whether this will be possible in the future if a newly created organ will fully remind a natural-occurring one. In such situation moral and ethical guards will raise a question of patenting life problem. To my mind, organ printing shall not be restricted because of entire similarity with a real one. A justification is that despite the fact that an organ is grown by virtue of using a real tissue, nevertheless, it cannot be obtained without a technological input and human's intervention, thus, it can be considered only is a half-natural, not a "naturally-occurring".

CONCLUSIONS

1. The first defence statement that ***the moral restrictions in patent law in most cases negatively influence on technological development and cause difficulties in assessing patentability of a specific technology*** is proven by the following conclusions:

1.1. As an example serves the U.S. courts' position where "technology" and "morality" are generally separated. If there is a debate between moral acceptability of an invention and invention itself as a promotion of new technology, unlikely courts will judge an invention as acceptable by the society; it will rather evaluate how susceptible it to other criteria for patentability.

1.2. Analysis shows that morality in human cloning is not one-sided. Cloning must not be perceived as undesirable and unacceptable technology because every step in biotechnology is potentially risky by itself. It should be welcomed in order to serve humanity in a proper way by virtue of diminishing severe health problems and life threats. Tools used in cloning must be as safe as possible and that is the task of biotechnologists to create a secure platform for its using in order to minimize potential hazardous outcomes.

1.3. CRISPR Cas9 tool regulation (law) should not strictly prescribe signatory states how to adjust their patent laws in order to match with international regulation.

1.4. Granting patents in 3-D bioprinting should be not restricted neither by moral and ethical concerns nor because of lack of technical feature. Deriving namely from a living organism, an organ printed on a special device, involving human intervention, cannot constitute the same as the real organ extracted from the body.

2. The second defence statement that ***society cannot serve as an indicator for what is moral and what is not*** is proven by the conclusions:

2.1. Using a term "society" gives no clear who is in charge, who is responsible and what are the criteria for selecting inventions as morally allowed or not.

2.2. It is a task of Patent Offices and courts to build up a logical and generally applicable scheme of determining morality aspects in inventions. Society can only serve as a supervisor over existing rules.

3. The third defence statement that ***it is rather difficult to reach the balance between the interests of technological advancement and the interests of society because the first has a faster pace than the law, however, the higher degree of equilibrium can be gained by virtue of mutual endeavors made by legislators, Patents Offices, courts and NGOs*** is proven by the conclusions:

3.1. In order to achieve balance between exclusive rights in biotechnological patents and interest of society, it should be taken into consideration that both sides have principally the main same interest – to evolve medical treatment and enhance genome sustainability towards genetic diseases.

3.2. Society should not be so opposing regarding new technologies in biology. NGOs, national governments should contribute into people's education and awareness regarding biotechnological inventions. That will reduce far-fetched views and prejudiced opinions about new technologies.

3.3. Without technology promotion and its *live application*, the mankind doesn't need it at all. Biotechnology is only worth protection and has the real value when it is industrially applicable. In addition, the Biotechnology Directive should be revised in respect of adding provisions about *genome editing tools*, 3-D bioprinting as well as rules distinguishing human embryo manipulations and embryo stem cells usage in technology.

RECOMMENDATIONS

1. The term “morality” should be maximally avoided in patent legal acts on EU level, it is more reasonable to introduce “ethics” instead. *Morality* is not a legal notion and it brings a lot of emotions into assessing technological adaptability.
2. CRISPR Cas9 should be introduced into European legislation. As a first step there must be a guideline which will encourage states to adopt genome editing as an innovative tool to deal with genetic diseases. It should not be anyway insistent in order not to “scare the society”.
3. EU legislator should add provisions concerning 3D bioprinting into Biotechnology Directive, EPC identifying the meaning of the technique, its purpose and acceptability to be patented.
4. As there is no single legal definition of what is considered to be a *human embryo*, it is necessary to add it to art. 2 of the Biotechnology Directive as well as EPC in order to reduce discrepancies in national laws. Author proposes to identify human embryo as the European Court of Justice in 2011 ruled in the case called Oliver Brüstle v. Greenpeace: “*Any human ovum after fertilization, any non-fertilized human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilized human ovum whose division and further development have been stimulated by parthenogenesis*”.
5. Using *human embryo stem cells* should be separately disclosed in the Biotechnology Directive as well as EPC as a patentable technique.
6. NGOs and various associations which supervise and evaluate technical advancement together with ethical problems (American Association for the Advancement of Science, The Commission's European Group on Ethics in Science and New Technologies etc.) should expand knowledge of the society about biotechnology by virtue of presentations, articles, social media in order to minimize resistance to new inventions in this field.

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ABSTRACT

This Master Thesis is dedicated namely to patentability in biotechnological inventions in two main jurisdictions – EU and the USA. The author concentrated primarily on the analysis of patentable subject-matter in biotechnological inventions, taking into account restrictions of patentability on different grounds, one of which is a highly debatable issue among scientists as well as lawyers – morality aspect. These objectives gave a possibility to broader understand the problem of fair balancing between interests of society and holders of monopoly rights, that in order to find out an equilibrium, all stakeholders (legislators, courts, patent offices, NGOs etc) should actively participate in minimizing opposition for both sides. Technology should be promoted and develop and, thus, the notion of morality should be crossed out from the legal texts and be changed on ethics as more scientific term.

Key words: biotechnology, 3-D bioprinting, genome editing, morality, patents.

SUMMARY
INTERNATIONAL (CROSS-BORDER) REGULATION OF BIOTECHNOLOGY PATENTABILITY

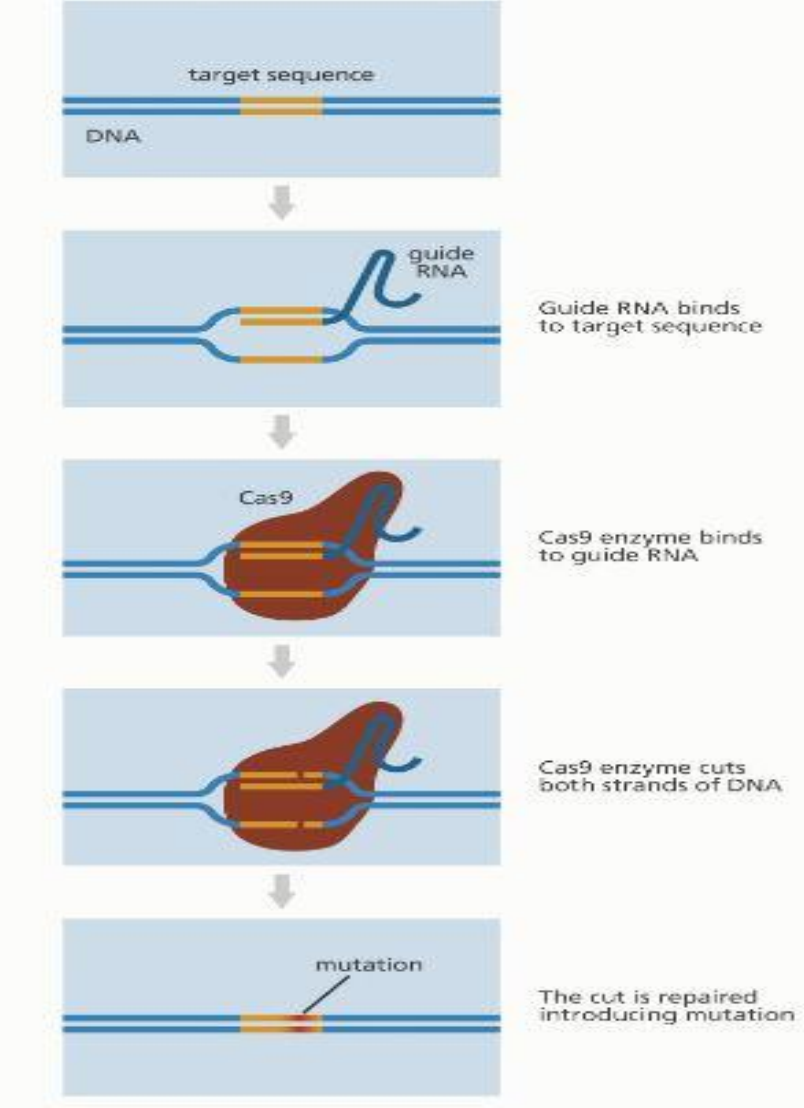
Intellectual property law and Biotechnology have a strong connection in the modern world. Pharmaceutical trade, medicine developments namely rely upon the development in inventions. On the one hand, companies involved in R&D in biotechnology make huge investments in order to obtain an appropriate invention which will work out in the real world and, thus, they are highly interested in returns from their input as fast as possible. On the other hand, the interests of the society. The latter is interested in safe, relatively cheap and highly qualitative technologies, especially in medical treatment. Unfortunately, as practice shows, it is not easy to reach fairness and to satisfy interests of all stakeholders at once. And one of the main issues which arises between two sides and that is envisaged by the author – is how dangerous new technologies can be to humans, their dignity, nature and environment on a whole despite their usefulness. Thus, the aim of this work was to find out the equilibrium between the interests of the society and holders of intellectual property rights, i.e. patents, on biotechnological inventions.

The aim of the work was achieved by virtue of analyzing what constitutes a patentable subject-matter in various jurisdictions, identifying ethical aspects in biotechnology, including separate analysis of human cloning, genome editing tools and 3D bioprinting. This Master Thesis comprises of 4 chapters covering historical developing of patenting on a whole as well as in biotechnology, general overview of patenting in civil and common law jurisdictions, including case law examples too, comparison of ethical and moral restraints in patent law in different spheres of biotechnology and main aspects of 3D bioprinting in modern patent law.

Taking into account all queries which author observed in her work, it can be concluded that morality issue per se in biotechnological patents is differently perceived by the common and civil law jurisdictions. On the top of that, morality should be definitely restricted in its influence on technical advancement and science on a whole. European Union regulation in this sphere should be more precise; morality as a notion should be changed to ethics as it has more scientific nature. In order to balance interests of scientific developers, business and society with the reference to moral issues, several steps should be made from various stakeholders (parliaments, Patents Offices, courts, NGOs etc).

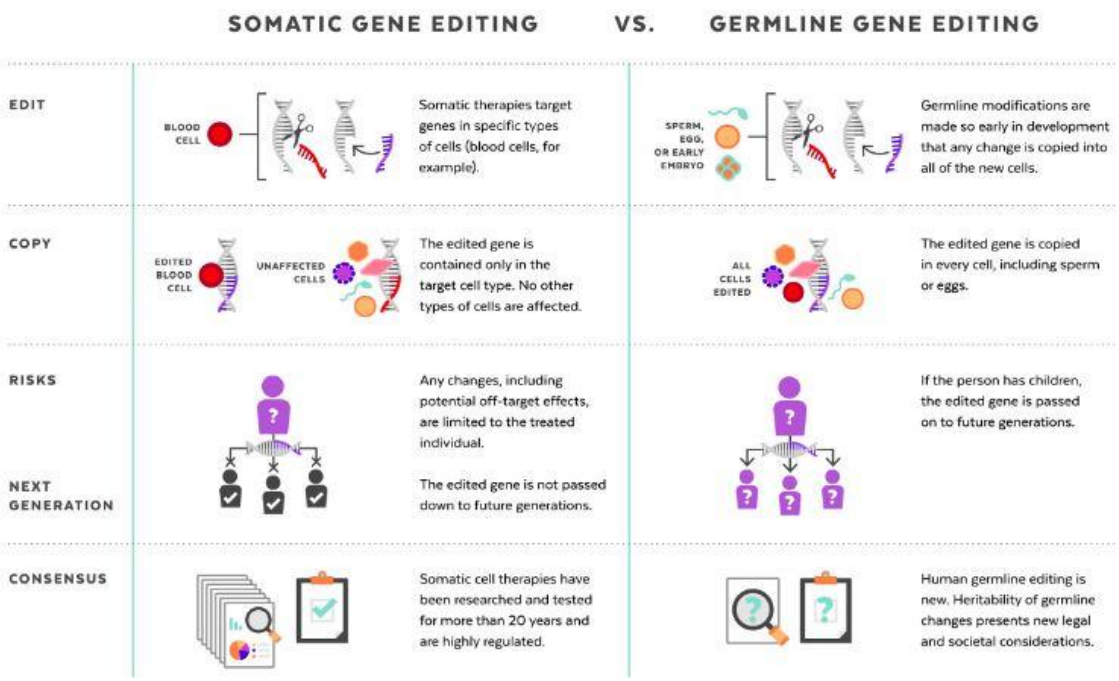
ANNEXES

Annex 1.[287]



[287] Illustration is taken from "What is CRISPR-Cas9?", Yourgenome.org, Image credit: Genome Research Limited, accessed 2019 April 30, https://www.yourgenome.org/facts/what-is-crispr-cas9

Annex 2.[288]



Annex 3.[289]

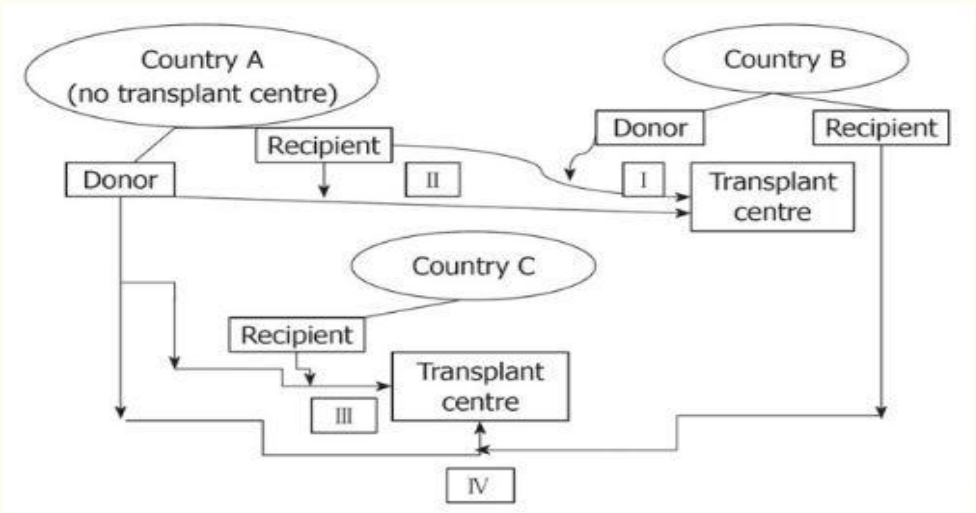


Figure 1

Types of transplant tourism. Model I: Recipient (R) travels to country B where donor (D) and transplant centre (TC) are; Model II: R and D travel to another country for transplantation; Model III: D travels to country C where R and TC are; Model IV: D and R residing in different countries travel to another country (C) for transplantation.

[288] Graphic by Judy Blomquist. "Perspectives on Gene Editing", The Harvard Gazette, 2019 April 30, https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/

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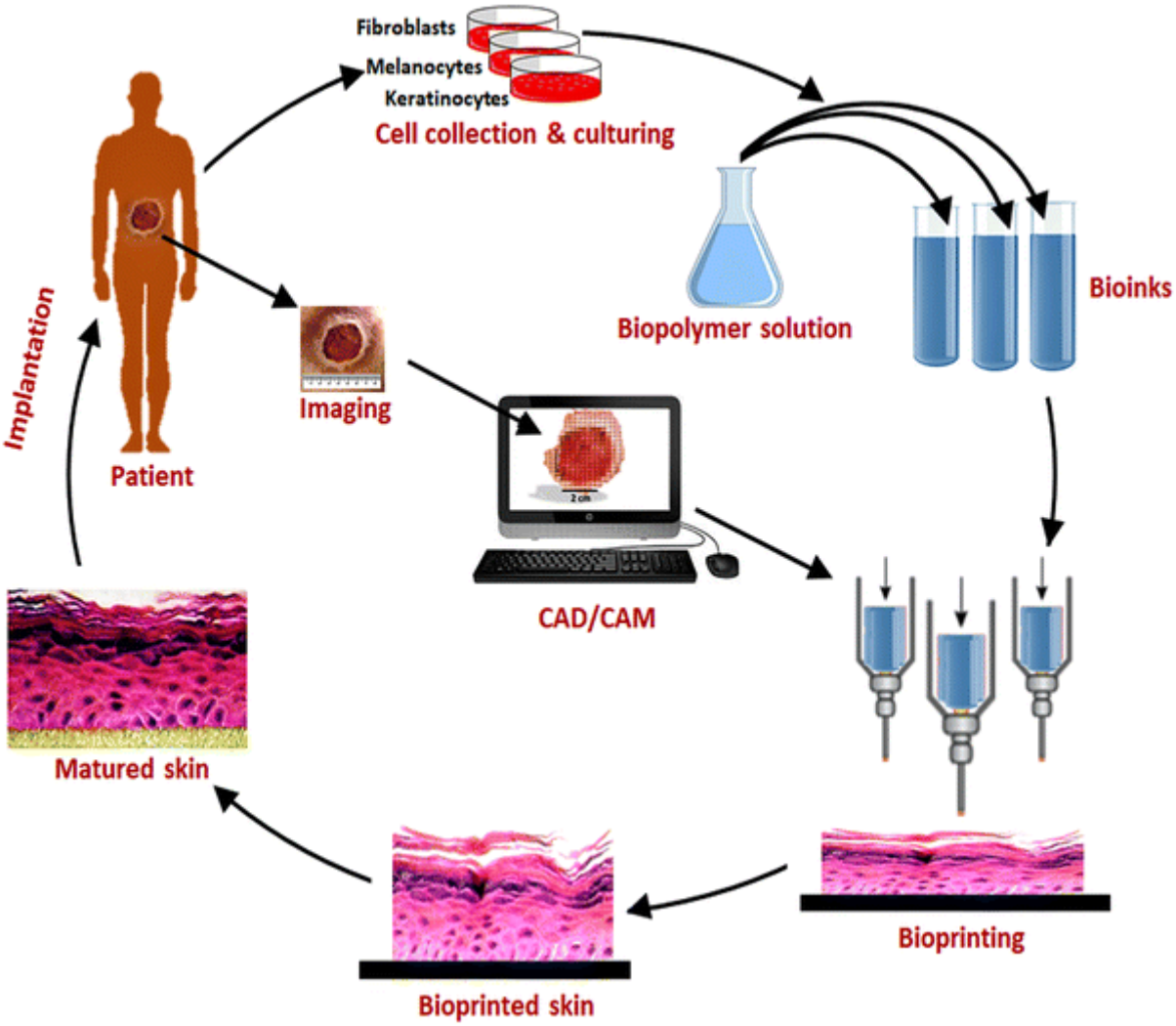
Annex 4.[290]



[290] Illustration is taken from Robin Augustine, "Skin bioprinting: a novel approach for creating artificial skin from synthetic and natural building blocks ", 2018 May 12, https://link.springer.com/content/pdf/10.1007%2Fs40204-018-0087-0.pdf

HONESTY DECLARATION

10/04/2019

Vilnius

I, Yevheniia Tkachova, student of Mykolas Romeris University (hereinafter referred to University),

Mykolas Romeris Law School, European and International Business Law Programme

(Faculty /Institute, Programme title)

confirm that the Master thesis titled

"International (Cross-Border Regulation of Biotechnology Patentability)":

1. Is carried out independently and honestly;
2. Was not presented and defended in another educational institution in Lithuania or abroad;
3. Was written in respect of the academic integrity and after becoming acquainted with methodological guidelines for thesis preparation.

I am informed of the fact that student can be expelled from the University for the breach of the fair competition principle, plagiarism, corresponding to the breach of the academic ethics.

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