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The legal and ethical aspects of gene technology

Doctoral Dissertation Theses

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Table of content

1. Research topic reasoning and project definition	3
2. Research methodology.....	5
3. The dissertation's structure	6
4. Summary of main findings	8
5. List of publications	11

1. Research topic reasoning and project definition

The future is inexhaustible. Although Aristotle had been dealing with the issue of transmitting hereditary information,¹ however, perhaps even he did not ever consider that a few thousand years later it would no longer be a question of how to transmit the genetic response from one living organism to another, but whether it is ethical or not.

When I chose genetic engineering as the topic of my dissertation, I wanted to explore not only the legal aspects but also the ethical lines of this unknown technology, first of all in order to get an accurate picture of what ethical rules preceded the legal regulations (such as the UNESCO international documents on bioethics), what the law utilised from these rules, and what the directions are that they may continue to serve as a basis for legal regulations.

The dissertation is strictly limited to genetic engineering procedures applicable to humans, such as human genetic testing, genetic engineering, as well as human genetic research, because at the beginning of the research I was curious about the human rights issues that human genetic engineering raise. Also, I wanted to address an area of genetic engineering that holds even relatively unfamiliar paths for the curious researcher.²

The aim of the dissertation is far from deterring people from engineering procedures, on the contrary, my objective is rather to draw the attention of legislators and the public to the issues and problems that need to be answered in order that genetic engineering may rather serve humans than turn against them. Setting the latter goal is essential because in the history of genetic engineering, humanity has repeatedly plunged into the mistake of differentiating people based on their genetic characteristics, thus deciding who is worthy of life and who is not (eugenic movements).

This is why it is important that the legal environment is well-prepared and able to respond in a timely manner to the new challenges that this unknown technology holds for it. However, it is also important to find a kind of harmony in the permission-restriction-prohibition triad as genetic engineering can offer a cure for diseases that have hitherto been considered incurable, therefore it can really benefit humanity.³ To achieve this, legislation is a major

¹ Siddhartha MUKHERJEE: *The Gene - Personal Story*, Park Publishing House, Budapest, 2017. p. 550.

² The legal regulation of genetically modified plants has been a topic discussed in great detail. Published on the topic without the need for completeness: János Ede Szilágyi, Gyula Bándi, Júlia Kovács Téglásiné, László Fodor, Judit Embersics (regarding genetically modified animals), Dr. Ágnes Kovács Tahyné

³ Such as the latest Hungarian development, the treatment of blindness with the help of gene therapy thanks to neurobiologist Roska Botond and his international research team. (Nikoletta

challenge, as legislators need to create (or rethink) rules that do not hinder the progress of science, but protect people from being the subject of irresponsible experiments.

Act XXI of 2008 on the Protection of Human Genetic Data, on the Rules of Human Genetic Studies and Research and the Operation of Biobanks seeks to address this challenge. Although the great merit of regulation is that it is really designed to regulate genetic engineering with respect for human rights and thereby seek to give maximum protection to human dignity. However, its disadvantage is that it does not address the issue of genetic engineering and the issues it raises: thus, what the permitted genetic engineering procedures are,⁴ and where the line between healing and repair lies. In my doctoral dissertation, I seek answers to such and similar questions in the light of the legal and ethical aspects of genetic engineering procedures applied to humans.

NAGY: A new science was born yesterday: we set out to cure blindness, 24.hu Science, May 25, 2021 <https://24.hu/tudomany/2021/05/25/roska-botond-vaksag-gyogytasa-genterapia/> (Download time: May 25, 2021)

⁴ However, the Act CLIV of 1997 on the Health Act provides a concise answer to this in section 182 (2) and states that it is possible to alter the genetic characteristics of embryos in the event that it is necessary for the prevention or treatment of the disease to the extent strictly necessary for the purpose.

2. Research methodology

The research methodology of the dissertation is adapted to the aim of the dissertation, after all not only the legal literature related to genetic engineering has been studied, but also the ethical literature dealing with genetic engineering, and most of the bioethical literature. However, in order to be able to provide a well-thought out picture of genetic engineering in humans in the dissertation, it was also important to review the history of genetic engineering, mostly based on scientific literature.

During the preparation of the dissertation I tried to make full use of the Hungarian legal literature, which is not rich in significant resources due to the novelty of the topic. I also aimed to give an international perspective on the topic due to the fact that the United States abounds in the legal, ethical, and scientific literature, thus the majority interesting case studies are included in such sources. For this topic, I used both Hungarian and EU legal regulations, as well as international ethical documents, which, although not binding, provided a great basis for subsequent legislation in this area.

It can be said that the dissertation takes a multidisciplinary approach to genetic engineering procedures in humans, which provides the analyst with a description of the legal and ethical aspects of technology, a critical approach to these trends, and questions that have not yet been answered. In the dissertation I aim not only to ask questions, but also to answer them. Due to the constantly changing and renewable technology, it is not necessarily possible to respond all these questions.

In accordance with the research methodology and the goal set, the dissertation is based on three main issues:

1. Is the regulation of genetic engineering sufficient enough or is it necessary to strengthen it in Hungary?
2. Is the protection of human dignity a sufficient reason for ...or will the concept of human dignity necessarily change as a result of innovation?
3. Does the perfection of a human being respond to the acceleration of evolution or does it rather mark the beginning of a new kind of eugenics?

3. The dissertation's structure

The dissertation starts with a short introduction in which the choice of the topic is explained and the structure of the whole dissertation is outlined. Then it reviews the above-mentioned theses and discusses the research methodology and also formulates the dissertation where human genetic engineering methods to be further discussed are located in the system.

The first chapter of the dissertation is about the history of genetic engineering, starting with the first thinkers pondering the possibility of passing on hereditary information, all the way to the Human Genome Program and the discovery of the gene map. It is already clear from this chapter that genetic engineering was initially used not only to cure humans or to explore the causes of hereditary diseases, but also to justify ideologies aimed at the mass extermination of humans (eugenic movements). The chapter also contains a separate historical overview of the development of human genetics in Hungary.

The second chapter provides an insight into ethics, especially bioethics, as the area of ethics that is most relevant to genetic engineering. The four principles of bioethics were formulated by Beauchamp and Childress as follows: 1. the principle of respect for autonomy, 2. the principle of harm, 3. the principle of charity, 4. the principle of justice, all of which must be borne in mind in human genetic engineering procedures. Even in the same chapter, I discussed the UNESCO documents on the relationship between bioethics and human rights, which, although do not have a binding force, but laid down many important rules in this area, thus laid the foundations for the legal regulation of human genetics. I also discuss the interesting question of whether our genes determine our behavioural patterns, the extent to which they affect intelligence, criminal propensity, sexuality, attention deficit, or even our religiosity or spirituality (god-gene).

The third chapter deals with the beginnings of the legal regulation of genetics, which unfortunately coincided with the heyday of eugenics, therefore from the United States of America through Switzerland to the former Soviet Union, countries passed their sterilization laws while Judge Holmes in 1926 rang their ears voiced his infamous sentence in *Buck v. Bell* that "three generations of the weak-minded are just enough." Nazi Germany only intensified these atrocities, and in addition to sterilization, euthanasia was introduced as "a way to purify the human race." After this period of human terror, it was the society of researchers that did not allow people to remember genetic engineering just because of the horrors, and they brought to life the Asilomar conferences from the 1970s. The purpose of the conferences was firstly to oblige researchers to recognise ethical and quasi-legal rules (mostly bans and moratoriums on

the applicability of certain technologies, such as recombinant DNA technology) and, on the other hand, also to create technologies such as CRISPR-Cas9 technology ("genetic engineering scissors"). The third chapter even addresses patent issues in genetic engineering, where there is a continuing confrontation between researchers' freedom of research, the financial interests of large corporations, and society's free (or even normal) access to technology. In addition, this chapter addresses the relationship between technology and law, while seeking answers to the question of how genetic engineering can be regulated. Furthermore, I deal with the concept of the gene as well as biotechnology, but since the concept of gene is also constantly evolving, it is not easy to define this otherwise intermediate legal norm legally.

The fourth chapter discusses the genetic engineering procedures used in humans themselves, as well as the human rights and sub-entitlements for which technology raises issues. The dissertation deals with human genetic research, genetic engineering, and human genetic research in a separate subchapter because I want to subordinate the legal regulation to technology, and not the other way around. I also intend individual human rights issues to appear one by one in relation to technology and the issues that arise in this way not to be missed. Thus, while there may be findings and issues that arise in multiple proceedings for individual human rights, their emphasis is essential to the protection of human rights. This is the chapter that mostly reflects on the main issues I mentioned in the research methodology, and thus seeks to answer the question of whether domestic regulation of genetic engineering is sufficient, and also whether the protection of human dignity can be a sufficient basis for a genetic innovation.

The fifth chapter provides an insight into the foreseeable future of genetic engineering, addressing the relatively new CRISPR-Cas9 technology, the phenomenon of biohackers, the possibility of cloning, embryonic stem cell therapy and the fundamental human rights that will continue to be important in the field of genetic engineering and human rights, the protection of human dignity, including the possibility of enhancing human capacity. In this chapter, I also deal with the development of technologies, the questions they raise and the possible answers to them. This chapter deals with the third major question posed at the beginning of the dissertation, namely whether human perfection can be seen as part of the evolutionary process (possibly accelerating it) or the beginning of a new kind of eugenics, as well as the transformation of the concept of human dignity.

This is followed by the conclusion of the dissertation, in which I provide an account of what answers can be given to the questions I have asked, as well to what extent my opinion differs from my initial position after the "completion" of the research.

4. Summary of main findings

One of the main findings of the dissertation is the answer to the theses, which can be found in the conclusion of the dissertation.

It can be said that I maintain my first statement regarding the domestic regulation it would be worthwhile including the regulation of genetic engineering procedures in Our Human Genetics Act separately, not only together with the prohibited, but also with the permissible procedures.

Furthermore, it would be important to regulate the special issues of the sale of DIY gene sets in Hungary as well. After all, with the help of these kits, anyone can become a geneticist in their own homes and enable themselves to modify genes without any prior knowledge or warning of the consequences.

Genetic tests taken by non-doctors should also be regulated, as these tests are freely marketable worldwide, but in addition to finding it amusing to know how many "prehistoric genes" we have, users of these tests are no longer aware of their, that their personal data, including their personal identification data and genetic patterns and data are stored by large companies and may be used for research.

It is also important to stop the phenomenon of „designer baby”, which the legislator is also pushing for, as this is not just a matter for the parents to decide which genetic disorder the embryo to be implanted into the mother's body has unless diseases detected by the procedure. The problem arises when society considers a banal disorder undesirable as blue eyes, which is also the result of a genetic disorder, so that parents can already intervene in traits that affect the child's health, are not relevant at all. Equally careful in maintaining social balance is the practice of some nations allowing parental non-preferences. In this case, however, the question is how to maintain gender balance: through parental intervention or natural selection in which case it is a question of whether the human race has already influenced this process similarly to the climate change. If so, nature may not necessarily be able to recover what humans have destroyed.

The dissertation presents the impact of genetic engineering on individual fundamental rights and their sub-rights, what new questions it may raise, what it can answer and what we cannot even guess the answers to. In connection with my second statement, I have come to the conclusion that the protection of human dignity is a paradox, because it can also be regarded as a violation of human dignity if genetic engineering interferes with human inviolability as a result, changes, moreover “improves” man). However, it is also a failure if in possession of the

technological knowledge medical science still does not benefit from genetic engineering because of fear. That is why I would not rule out the possibility of extending the concept of human dignity with new meanings to social pressure, but I would also emphasize that the fundamental value of human dignity should not be in this case. In such a situation, the question to be decided may be what violates a person's inviolability and what does not yet qualify as such, for example, to which group the capacity enhancement can be classified. In the case of capability enhancement, it is important to clarify that non-genetically based capability enhancement (glasses, wearable robotic arm, doping agents) should be separated from genetically ones. While the former non-genetic enhancement is only allowed to a certain extent, consequently the short-sighted can wear glasses to improve their vision, athletes can take protein powders to grow their muscles, but other doping preparations are not permitted to be used to achieve better results in competitions. In short, genetic enhancement would need to be differentiated from healing the following way: while healing is aimed at restoring normal functioning of the body, enhancement would focus on abnormal functioning (e.g., a blind person could not only regain full vision, but he could see much better than before and also read the serial numbers of planes even from great distances of ten thousands of kilometres altitude).

As for the third statement, I would stress that the law must be able to pursue the new kind of eugenic endeavors in its infancy and do its utmost to prevent discrimination based on genetic characteristics. Thus, it must be possible to stop new forms of eugenic endeavors by means of furthermore, by informing and teaching society so that history does not repeat itself and acts of horrific acts against humanity will not take place in the hope of creating a 'pure race', such as the ones that happened during World War II and before due to sterilization laws.

It is necessary to start this process not only so that such horrors will not take place, but also so that in the future we will not differentiate human beings according to who has undergone genetic modification (and thus became a superman) and who is not. Of course, there may be two groups of people who have undergone genetic modification: one of whom may be those who have been healed by the gene therapy method and the other group may include people who, as a form of plastic surgery, want to achieve self-improvement with this method.⁵ The

⁵ In 2017, Josiah Zayner, a former NASA engineer who intended to demonstrate that gene therapy is for everyone, gave himself a live gene therapy injection on social media in the United States of America. Although I do not agree with his message, and I think it would be important to emphasize that gene therapy belongs to everyone, not just to a privileged layer. However, I do not agree with his method, he was completely irresponsible and did not think at all about giving himself a gene therapy injection regardless of what it affected or did not affect at all), which endangered the common heritage of mankind consequently our genes. He did so despite

problem in this case would be exacerbated to the greatest extent if people who have undergone genetic modification, would acquire additional rights and society would split into a group of genetically modified and non-genetically affected people. Not only would this deepen the social gap that already exists, but we could easily find ourselves going out of fashion and losing the human rights that we have by birth just because we do not take advantage of gene therapy.

With regard to human genetic procedures, it is important to see that technology is not yet there to cure all diseases, and that gene therapy methods present in clinical practice are not routine procedures, either. However, people and perhaps researchers alike need to be made aware, even if they already know it, that our genetic knowledge is still in its infancy and genetic processes in human bodies are extremely complex and intricate. For this reason, it may easily occur that while one gene has been modified, therefore a disease of expected genetic origin is eliminated in the individual organisation but at the same time due to the impact of the modification in the gene a more serious condition may replace it. That is why it is essential for researchers, patients and legislators alike to be proactive and recognise what procedure can be allowed to enter the research phase at all and what should rather be banned by law or imposed a professional moratorium on at least.

Hopefully humanity will succeed in learning from the mistakes of the past. Even if there are always some individuals who wish to “take advantage” of technological innovations at will and show the world what they are capable of, simultaneously there will also be people, and let us hope they will be internationally be in majority, who will be able to curb unknown technologies, among the others human genetic engineering.

many states prohibit genetic engineering methods. Even those states which allow the use of such procedures usually only by using other therapeutic solutions in addition to gene therapy on the person struggling with the disease. However, Zayner did not want to cure his illness with gene therapy, but rather aimed at civic popping and raising awareness.

5. List of publications

1. Human genetic testing and the right to information, In: Péter Miskolczi Bodnár (ed.): XII. National Professional Meeting of Doctoral Students in Law, Law and State, No. 22, Budapest, 2018. pp. 430-437. https://ajk.kre.hu/images/doc4/dokumentumok/Allam_es_Jog_22_XII_Doktorandusz_konferencia.pdf
2. The problem of the feasibility of the right to information in the age of genetic engineering, In: Dr. István Koncz - Ilona Szova (ed.): The 15-year-old PEME XVI. PhD - Conference Lectures, Electronic Book, 2018. pp. 87-99. <https://peme.hu/wp-content/uploads/2018/05/XVI.-PEME-Konferencia.pdf>
3. Human rights in the shadow of genetic engineering, In: KRE-DIt, 2018/1., <http://www.kre-dit.hu/tanulmanyok/szutor-vivien-az-emberi-jogok-a-gentechnologia-arnyekaban/>
4. The problem of the appearance of individual human rights in genetic engineering procedures. In: Glossa Iuridica, a journal of the Faculty of Law of the Károli Gáspár Reformed University, "Good Governance", volume 1-28, 2018. No., Budapest, 2018. pp. 158 - 191. https://ajk.kre.hu/images/doc6/kiadvanyok/Glossa_Iuridica_2018_1-2_szam.pdf
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6. General and special rules of human genetic research, XIII. National Professional Meeting of Doctoral Students of Law - Károli conference volume, 2018, pp. 261-268. https://ajk.kre.hu/images/doc5/konferencia/merge_from_ofoct_20.pdf
7. Human dignity in genetic engineering, In: Oguz Kelemen – Gergely Tari (ed.): The Bioethics of the „Crazy Ape”, Trivent Publishing, Volume 2, 2019 (April), ISBN 978-615-81222-8-3 (print), ISBN 978-615-81222-9-0 (online), <https://trivent-publishing.eu/books/thebioethicsofthecrazyape/2.%20Vivien%20Szutor.pdf>
8. Opportunities for people with disabilities in the age of genetic engineering, XIV. National Professional Meeting of Doctoral Students in Law, Law and State, No. 24, 2019, pp. 407 - 416. http://kre.hu/ajk/images/doc5/konferencia/merge_from_ofoct_19.pdf
9. Opportunities and legal challenges of genetic engineering, XVI. National Professional Meeting of Doctoral Students in Law, 2020, pp. 275 - 281.

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