Katarzyna CHAŁUBIŃSKA-JENKIEWICZ[1] DOI : 10.32055/mw.2020.14.9

Ethics and law in biotechnological inventiveness on the example of human genetic engineering[2]

The civilizational development connected with the progress of the so-called "new technologies" contributes not only to the improvement in living standards of an individual but also to the emergence of newer and newer threats which touch the axiological area of an individual. The law seems to a natural instrument for a human being and, in accordance with the adopted regulatory policies, affects the areas of human activities where self-regulation or codes of ethics cannot fulfill the social and individual expectations. In the current conditions of civilization, the necessary diagnosis of the state of respect adopted in constitutional value systems is becoming an increasingly important challenge for the state.

Such analysis aims at ensuring the proper functioning of an individual and society in the world of new technologies. This issue mainly concerns a human being in scientific development and research[3], especially robotics and biotechnology. The area of new technologies may become a place for implementing important public tasks related to the development of the individual, society, and respect for his axiology. As Ithiel de Sola Pool notices in the context of new technologies, "in fact, it is not about control over new technologies, but it is about control over the crumbling world[4]". It seems that in the face of numerous threats related to creativity primarily based on the development of new technologies, legal regulation should require to ensure the protection of individual rights and freedoms, pursuing the same objectives of public interest. However, we have to emphasize the existence of a boundary which states the limits of the nature of science, and the practice of science cannot be a cover for the acts violating the law and rights of other persons. According to this view, it is possible to differentiate the sphere of uncontested fact requiring superior protection against falsehood and the sphere of evaluation of these facts aiming not at questioning them, which seems crucial for the assessment of human status in the modern world.

---

[1] Asst. prof. of legal sciences in the discipline of law, Assoc. prof. at the Academy of Martial Arts, Institute of Law and Defense Administration, ORCID 0000-0003-0188-5704.

[2] This part of the expert opinion was discussed in K. Chałubińska-Jentkiewicz, M. Karpiuk, *Prawo nowych technologii*, Warsaw 2015. In this work, the issues discussed here have been updated and supplemented.

[3] Cf. T. Twardowski, *Aspekty społeczno-prawne biotechnologii w Polsce. Wynalazczość i ochrona własności intelektualnej – ochrona prawna rozwiązań biotechnologicznych*, Bulletin no. 16, Polish Chamber of Patent Attorneys, Kielce 1996, pp. 8–16, and also see T. Twardowski, A. Twardowska, *Refleksje biotechnologa i rzecznika patentowego*, in: *Księga pamiątkowa z okazji 85-lecia ochrony własności przemysłowej w Polsce*, Warsaw 2003, pp. 335–344. Decision of the Constitutional Tribunal of 8 March 2011, file ref. act K 29/08.

[4] I. Pool, *Technologies of freedom*, Cambridge 1983, p. 79, after: K. Chałubińska-Jentkiewicz, M. Karpiuk, *Prawo nowych technologii*, Warsaw 2015.

In the context of the development of research and science, one of the critical values which must be taken into account in this analysis and which is mentioned in Article 38 of the Constitution of the Polish Republic is to ensure that the Polish Republic provides legal protection of life. In Article 39 of the Constitution, the legislator has adopted the rule that no one can be subjected to scientific experiments, including medical experiments, without his/her voluntary consent.

A human being is not only the initiator of research but also its subject. All the problems related to the development of science and research will mainly concern philosophical issues and applicable axiology. Thus, determining the moment of the beginning of human life – the moment of conception raises legal doubts. What kind of criteria should we apply?

Should we consider the criterion of the moment of conception, the so-called embryonic (extended to the first two weeks of pregnancy) or the genetic criterion (human being is a fetus from the second week of life) or morphological criterion (about 16 weeks of pregnancy), or the criterion of survival outside the mother's body (from about 22–23 weeks of pregnancy) and finally, the criterion of birth[5]. International documents concerning this fundamental law, the right to live, do not treat it as an absolute value.

The right to live is not absolute in the regulations of EKPC; it corresponds with such problems as abortion, euthanasia, cloning, death of *sense largo*[6]. According to the international community, it is not clear from which moment human life should be protected. EU legislator did not go any further into specific areas of human activity concerning the use of biological materials of human origin but left unsolved morally controversial solutions causing problem build-up in the increasingly developing biotech industry. It is worth mentioning that modernity somehow gives incentives to the innovative approach and analysis of the law, also in the context of regulating what seems complicated, unclear, incomprehensible, or examined only to a small extent[7]. Making all these issues clear and well-defined requires consideration of the law in connection with other laws in the concerned document. Still, even this activity is not always enough to understand the essence of this law, leaving many issues for free interpretation[8]. However, the development of new technologies requires that the issue of the boundaries of science in the context of human rights should be raised at the same time.

It should be emphasized here that in art. 2 (Primacy of the human being) Convention for the Protection of Human Rights and Dignity of Human Being in the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (accepted on November 19th, 1996)[9], it was accepted that the benefit and well-being of a human being predominate the exclusive benefit of society or science. Thus, the research in biol-

[5] Ibidem, p. 50.

[6] M. Błażewicz, *Prawo do życia*, in: *Prawa i wolności I i II generacji*, eds. A. Florczak, B. Bolechowa, Toruń 2006, p. 40.

[7] Also M. K. Borowik, *Ochrona patentowa wynalazków biotechnologicznych w świetle zdefiniowania pojęcia embrionu ludzkiego w orzecznictwie TSUE*, „Internetowy Przegląd Prawniczy TBSP UJ" 2017, issue 2.

[8] K. Przybyszewski, *Prawa człowieka w kontekstach kulturowych*, „Pisma Filozoficzne" 2010, vol. 116, p. 105.

[9] Open in Oviedo, 4 April 1997.

ogy and medicine may be conducted independently, subject to regulations ensuring the protection of human beings. However, in accordance with art. 18 of the Convention, if it allows research on embryos *in vitro*, it should provide adequate protection of the embryo, and the Convention prohibits the embryo creation for the sake of science. Of course, these regulations do not directly solve the problem of determining the answer to the question about the legal status of a conceived child. This approach is due to the nature of the research in biotechnology and the development of possible interference not only with living conditions, its quality but also its sense.

"New technologies of genetic interference have set people a new, higher place in space […] Copernicus and Darwin degraded a human being, taking his place in the centre of the universe, but new biology will replace him his key role" – says Robert L. Sinsheimer, a molecular biologist at the California Institute of Technology, describing the future of genetic engineering[10]. Such a possibility of improving a human being, as Michael J.Sandel points out, is a side effect of biomedical progress. Genetic revolution broke out there to cure the disease but now tempts us with the prospect of improving our results, designing our children, and improving our nature. However, this picture does not have to be true. Genetic engineering can be interpreted as the ultimate expression of our desire to rule over the world and our own nature. And such a vision of freedom is deceptive. Accepting it, we risk that we stop appreciating life as a gift and that the only value we can appeal to will be our will[11]. Michael J. Sanders refers to stem cell cloned blastocyst research, justifying it by religious and similar views, especially Kant's dualism (everything is either a person worthy of respect or a thing which can be used). According to him: "The use of genetic engineering in order to create children a la minute is an extreme expression of pride, which shows the loss of respect to life as a gift. However, the research on stem cells carried out to cure serious diseases using unimplemented blastocysts is a noble example of the application of human ingenuity to promote health and help people to play a proper role in the process of repairing the reality".

The author emphasizes, however, the necessity of creating regulations that present moral restraint, adequate in a situation of conflict with the ethically unresolved mystery of the beginning of human life. The questions which appear in the time of the development of biotechnology are to determine the boundaries of the intervention of science and therefore refer to the issues of standardized limitations, which will constitute the basis for the activities of public authorities in this new and so far, undeveloped area. These considerations relate to eugenics, which can be described as the struggle to improve the genetic structure of the human race. It should be emphasized that the development of medical research, which primarily aims at restoring normal functions of the body, requires human intervention, but in the atmosphere of respecting the idea of life, social abilities, and achievements as a gift. Thus, the man and his life become the epicenter of these activities.

---

[10] R. L. Sinsheimer, *The prospect of designed genetic change*, „Engineering and Science Magazine" 1969, April, reprinted in *Ethics, reproduction and genetic control*, ed. R. F. Chadwick, Londyn 1994, pp. 144–145, after: M. J. Sandel, *Przeciwko udoskonaleniu człowieka. Etyka w czasach inżynierii genetycznej*, Warsaw 2014, p. 89.

[11] M. J. Sandel, op. cit., p. 90.

Meanwhile, the issue of eugenics and the development of other branches of genetic engineering in social, legal, and ethical aspects seems to be in the initial stage of discourse. Currently, technological processes overcoming nature and directly and deeply interfering with the life of a human being are only preliminary analyzed and attempted to be morally assessed. The next important issue is rather legal restraint regulation because its very extent of interfering with science that is a regulatory sphere, will provide the future moral foundations and directions of development of genetic engineering and thus human life and the future of entire humanity.

The state policy expressed on the basis of laws in the field of industrial property, including patent law, should take into account an axiological factor, and in particular, respect the provisions of the Convention of June 5th, 1992, on Biological Diversity. According to art. 1 of the Convention on Diversity, the purpose of regulation is the protection of biological diversity, sustainable use of its elements, and honest and fair sharing of benefits of taking advantage of genetic resources, including appropriate access to genetic resources and proper transfer of adequate technologies respecting all legal rights to these resources and technologies, and finally adequate funding. According to the Convention, each involved party, if possible and necessary, should (a) include the issue of protection and sustainable use of biological resources in the decision-making process at the national level, (b) apply the measures on taking advantage of biological resources to avoid or reduce adverse effects on biological diversity; (c) protect and encourage customary use of biological resources following traditional practices of culture which are in accordance with nature protection and sustainable development; (d) provide assistance to local communities in the assessment and application of corrective actions in degraded areas where biological diversity has been reduced; (e) encourage cooperation between its governing bodies and its private sector in developing methods supporting sustained usage of natural resources (art. 10).

Additionally, in art. 16 of the Convention, it is stated that each party involved recognizing that technology includes biotechnology and that the access to technology and its transfer between contracting parties are the necessary conditions for fulfilling the targets of this Convention. It obliges, as per the provisions of this Article, to provide and also facilitate access and transfer of these technologies to the other contracting parties, which are essential for the protection and sustainable use of biodiversity or make use of genetic resources and do not cause significant damage to nature. The access to technology and its transfer to developing countries should be provided and also facilitated on fair and most favorable conditions, including preferable terms or concessions if the parties have agreed, and if necessary, following the financial mechanism stated in the Convention. In the case of technologies which are subjects to patent law or other intellectual property rights, such access and the transfer takes place under the conditions that ensure their adequate and effective protection in accordance with the rules of intellectual property rights. According to the Convention, each contracting party shall undertake the appropriate legislative, administrative, or political measures to ensure the contracting parties, especially the countries which provide genetic resources, access to technology based on the use of genetic resources on mutually agreed terms, including patent and other intellectual property regulations laws protected technology. Each contracting party also undertakes appropriate legislative, admirative, and politi-

cal activities that encourage the private sector to facilitate access to technology and its transfer and joint projects in technology development. Such activities bring benefits to both government institutions and the private sector as well. The Convention also includes the principle of respecting the right of its Member State to its genetic resources.

The Convention on Biological Diversity was signed on June 5th, 1992 by the European Community and its Member States at the Conference of United Nations on environment and development (UNCED), known as Earth Summit, which took place in Rio de Janeiro (Brazil). This Convention was approved on behalf of the Union by Council Decision 93/626/EWG of October 25th, 1993[12]. According to art. 1 of the Convention, its objectives are as follows: protection of biological diversity, sustainable use of its elements, and fair and honest sharing of benefits from the usage of genetic resources. To fulfill these purposes, the Convention imposes the following obligations on the contracting parties:

1) developing national strategies, plans, and programs referring to conservation and sustainable use of biological diversity, and including all these elements in appropriate national projects, programs, and policies (art. 6);
2) the identification and monitoring of elements of biological diversity and risk factors (art. 7);
3) adopting protection measures in situ and ex situ (art. 8 and 9);
4) adopting measures facilitating sustainable use of biological diversity elements, scientific research and training, education and social awareness, research on the impact of projects on biological diversity, access to genetic resources and technologies (including biotechnology), and information exchange and scientific and technical cooperation (art. 10–18).

Article 19 para. 3 of the Convention provides that: Parties shall consider the need for setting and maintaining a protocol stating appropriate procedures, especially about obtaining the prior consent of safe transfer, handling and use of all living organisms modified as a result of biotechnology, which may have a negative impact on protection and sustainable use of biological diversity. In turn, in art. 27 para 2 TRIPS[13], a provision was introduced that all members of the agreement may exclude from patentability all inventions which are not allowed to be traded on their territories because of the need to protect public order and morality, including life and health protection of humans, animals, and plants, or to prevent serious damage to the

[12] O.J. of E.E.C. L 309 z 13.12.1993, p. 1.

[13] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 235, annexed to the Agreement establishing the World Trade Organization (WTO), done in Marrakesh on 15 April, 1994. Agreement establishing the World Trade Organization (WTO), done at Marrakesh on April 15, 1994 r., Journal of Laws of 1995, No. 98, item 483 as amended. According to art. 1 p. 2 AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: "For the purposes of this Agreement, the term 'intellectual property' refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II, i.e. Copyright and Related Rights, Computer Software and Data Bases Trademarks, Protection of Performers, Producers of Phonograms (sound recordings) and Broadcasting Organizations, Geographical Indications, Industrial Designs and Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information. The Annexes to the Agreement were published in the Announcement of the Minister of Foreign Affairs of 12 February, 1996 on the Publication of Annexes to the Agreement establishing the World Trade Organization (WTO)" (Journal of Laws No. 32, item 143).

environment, provided that such exemption is not made simply because such use is prohibited by national law.

In art. 53 lit. and the Convention on granting patents in Europe signed in Munich on October 5th, 1973[14] signed by European Union countries, there is a ban on granting patents for inventions of which publishing or applying would be in contradiction with public order or morality provided that it is not regarded as contradictory mainly because it is prohibited by law or any other legal act in several or all contracting states. Pursuant to art. 1 of the Charter of Fundamental Rights of the European Union, human dignity is inviolable and must be respected and protected. Article 3 of the Charter of basic laws states that everyone has the right to respect his physical and mental integrity. In medicine and biology, a total ban on using the human body and its separate parts for any profits must be respected.

The issue of biotechnology regulates Directive 98/44/EC of the European Parliament and the Council of July 6th, 1998 on the legal protection of biotechnological inventions[15]. The European legislator stressed that the aim of Directive 98/44/WE is not only establishing a framework of the legal protection of biotechnological inventions, particularly to maintain and encourage investment in the field of biotechnology, but also to remove some differences in legislation and practices of Member States in this area. According to art. 1 point 1 of the Directive 98/44/WE, Member States shall protect biotechnological inventions under the national patent law and, if necessary, adjust their national patent law regarding the provisions of this Directive.

Having in mind a specific character of patentability in the range covering "subjectively" living matter, the Directive mentioned above sets limitations in the aspect of what bear patentability (and thus becomes subject of protection) and what does not have patentability (due to subjectivity). And so, art. 3 of the Directive 98/44/WE states that patentability can be assigned to new inventions, obtain some inventive level, and are suitable for industrial application even if they refer to the product consisting of or containing biological material or a method through which this biological material is produced, processed or used. Article 3 paragraph 2 of the Directive 98/44/WE also states that the subject of an invention may be biological material, which is isolated from its natural environment or produced employing a technical process, even if it previously occurred in nature. However, pursuant to art. 5 paragraph 5 of the Directive 98/44/WE: "Human body in various stages of its formation and development as well simple discovery of one of its elements […] cannot be regarded as a patentable invention. According to art. 5 paragraph 2 of the Directive 98/44/WE, it is recognized, however, that an element isolated from the human body or otherwise created by means of any technical method may be regarded as a patentable invention, even if the structure of this element is identical with the structure of a natural element ("artificial skin" is an example of such an invention). Article 6 of the Directive also states a possibility of the patent prohibition. This provision reads as follows: "Inventions should be considered unpatentable when their commercial use would be contrary to public order or morality; however, this use is not considered to be contradictory only because it is prohibited by statutory and executive laws. 2. Pursuant to paragraph 1, it is considered as not

[14] Journal of Laws of 2004 No. 79, item 737, as amended.

[15] O.J. WE L 213 of 30 July 1998, p. 13.

having patentable abilities [...] c) the use of human embryo for industrial or commercial purposes. It should be noted here that the Directive 98/44/WE in the name of the principles of protection of dignity and integrity of a human being, prohibits granting of the patentability to the human body in various stages of its formation and development including embryo cells"[16].

Thus, it is clear from the Directive that the protection of human dignity is the principle applied not only to an existing human being that is to a newborn baby but also a human body from the first stage of its development, that is, from the moment of conception. Therefore, you should accept the statement that legal regulations of industrial property are the source of formal and legal arrangements about when life begins and since when human life should be protected legally.

According to motif 39 of the Directive, public order and good morals are particularly responsible for ethical and moral principles approved by the Member States which should be observed carefully in the field of biotechnology because of the potential scope of inventions and their inherent connection with living matter; these ethical and moral principles complement standard, patentable studies regardless the technical sphere of the invention.

Simultaneously it was decided that the interventions in the human germline and human cloning violate public order and good morals; it is, therefore, important that the patent for modifying the human identity of human germline and human cloning (motif 40) are explicitly excluded. The exact method of human cloning can be defined as any other method, including embryo splitting techniques, designed to create a human being with the same nuclear genetic information as any other living or deceased human being. As Michal du Vall emphasized: "a number of risks is connected with the development of biotechnology and certain expectations are connected with the results of granting patents to their inventions. Furthermore, it is pointed out that the side effect of the emergence of more valuable plants and animals from the economic point of view leads to the outcompeting of already existing species or breeds. In a longer perspective, it may lead to the loss of biodiversity in specific areas of human activity"[17] "Thus, in the above-mentioned scope, it is crucial to determine when we are dealing with a human embryo. In art. 6 lit. c of Directive 98/44/WE, a notion of the human embryo was introduced but no legal definition. This notion covers biological material from the stage of fertilization, primary totipotent cells, and all subsequent processes of development and formation of the human body. Therefore, we should acknowledge that an embryo is a blastocyst, unfertilized egg cells in which a cell core of a mature human cell was implemented; or these cells which were stimulated to further development and division by parthenogenesis are also regarded as embryos while the application of these techniques leads the acquisition of totipotent cells. Single embryo stem cells of pluripotent nature cannot be covered by this concept since they are not able to develop into a human being. According to the Directive, an invention should be deprived of patentability if the technical use of the patented method requires prior destruction of human embryos or using them as a scientific material even if the description of this method does not contain any reference to human embryo usage. The exemption from

[16] Cf. Art. 5 sec. 1, and also motif 16 of that Directive.

[17] M. du Vall, *Prawo patentowe*, Warsaw 2008, p. 24.

this patentability ban of using human embryos for industrial or commercial purposes refers only to inventions serving therapeutic or diagnostic purposes related to the human embryo and are useful for it" (motif 42 of Directive 98/44/WE).

According to the opinion of the European Group on Ethics in Science and New Technologies, creating human embryos to obtain stem cells is not to be accepted from an ethical point of view (see point 2.7 of an Opinion number 15 from November 14th, 2000 on ethical aspects of the research on human stem cells and their use, available on the website of the group). On the other hand, Yves Bot, a chief spokesman in his opinion, presented on March 10th, 2011[18], stated that the notion of the human embryo should be understood in the same way in all the Member States of the European Union. Such an appeal can be justified by the fact that the EU is not only the market but an organization at the same time, and it is based on shared values that should be introduced to life. The principle of human dignity had been recognized by the Tribunal as a general rule of the law even before it was written in art. 2 TUE as a value on which the UE is based on. According to the spokesman, basic assumptions of various philosophical and religious systems are concentrated around the definition of an embryo. Therefore, such a definition can be worked out only based on the legal analysis carried out on the principles, which are objective and established on science. The same concern for maintaining objectivity leads to the conclusion that the silence of science or failure to demonstrate something should be considered as objective information on which a legal analysis, as indicated above, can be based. And there are no legal objections to taking a favorable position deriving it from the superior law, which is dignity and deriving from it – the most important – the right to life. Therefore, the developed definition would only be relevant to a specific regulation. According to the spokesman, the consequence of leaving the difficulty of defining the notion of the human embryo to the Member States, with the awareness of the existing differences in this respect, would be the situation when an invention could become patentable in the individual Member States. At the same time, in the other Member States, its patentability would be banned. Such a situation would violate the primary aim of the Directive, which is to establish effective and harmonized protection of biotechnological inventions.

According to the spokesman's opinion, the human body will be the subject of the definition, not the very moment when *in utero,* which may be a cluster of cells, changes its character and even if it does not become a human being, it is the subject of the law, and even a legal entity and what is essential is not the wording and attitude taken in this regulation which due to the terminology used in it leads not to defining of life itself but to the definition of the human body. Indeed, it is the human body in various stages of formation and development, which is protected by the Directive, stating clearly that it is excluded from patentability. Thus, an embryo will be each stage of the development of the human being, including the stages in which totipotent cells are being replaced by pluripotent cells (i.e., blastocyst stage – if totipotent cells can transform themselves into a fully developed human body; the blastocyst is a temporary result of this ability of this development. Therefore, the blastocyst is one of the aspects and stages of the development of the human body). On the other hand, this status cannot be assigned

[18] Case C-34/10, *Oliver Brüstle vs. Greenpeace eV*, Zb. Orz. (Collection of Jurisprudence) 2011, p. I-9821.

to single embryonic stem cells because these cells themselves cannot transform into the human body. However, they cannot come from a blastocyst. Such cells taken from a human embryo in the blastocyst stage inevitably mean destroying a human embryo. According to the spokesman: "If we allow the industrial application of the invention based on embryonic stem cells, it would mean permitting the use of the embryo as ordinary scientific material. This kind of invention would lead to the instrumental treatment of a human body in its first stages of its development".

In the above-mentioned case, the economic issues related to the refusal of giving patentability to the human body were thought to possibly affect the research negatively. However, according to the spokesman, the problems of patentability are not necessarily closely connected with scientific research. The Member States have the freedom to consent to carry out scientific research under the conditions set out by them. Patentability that is launching the product after meeting specific production criteria stated in the patent itself should be, in fact, in accordance to the conditions stated in the Directive 98/44/WE in order to harmonize, which takes into account all the ethical aspects in such a way as to avoid situations in which economic functioning of the market would create competition requiring the sacrifice of the value of human dignity[19].

In the Polish legal system, the issue of a biotechnology invention is regulated by the Act of June 30th, 2000 – Industrial Property Law[20]. Within the meaning of art. 93 human body shall not be regarded as an invention, in its various stages of formation and development or ordinary discovery of one of its elements, including the sequence or a partial sequence of a gene. For biotechnological inventions which use would be in contradiction with public order or morality within the meaning of art. 29 paragraph 1 point 1, or public morality one considers the following:

1) ways of human cloning,
2) ways of modifications of genetic identity of the human germline,
3) the use of human embryo for industrial or commercial purposes,
4) processes of modifying the genetic identity of animals, which may cause suffering without any substantial medical benefits for a man or an animal, and animals, which are the result of the application of such methods.

The registration of the invention concerning a sequence or a partial sequence of a gene should reveal their industrial application. However, the human body shall not be regarded as an invention in any of its stages of formation and development and

[19] On this subject cf. M. du Vall, op. cit., pp. 344–392; J. Kondratiewa-Bryzik, K. Sękowska-Kozłowska, *Prawnopatentowe instrumenty przeciwdziałania niepożądanym skutkom wyłączności patentowej*, in: *Prawa człowieka wobec rozwoju biotechnologii*, Warsaw 2013, p. 56; H. Żakowska-Henzler, *Ochrona patentowa wynalazków biotechnologicznych*, Warsaw 2013, also, *Wynalazek biotechnologiczny: przedmiot patentu*, Warsaw 2006; T. Twardowski, A. Twardowska, *Protecting Biotech Invention Rights*, „European Biotechnology Science Industry News" 2004, no. 3, p. 28; H. Żakowska-Henzler, *Ochrona prawna wynalazków biotechnologicznych w świetle Dyrektywy nr 98/44 z dnia 6 czerwca 1998 r.*, „Studia Prawnicze" 2000, no. 1–2, p. 106; E. Nowińska, U. Promińska, M. du Vall, *Prawo własności przemysłowej*, Warsaw 2005, p. 54; J. Fiołka, *Projekt Wytycznych Rady Wspólnoty Europejskiej w sprawie ochrony prawnej wynalazków biotechnologicznych*, „Zeszyty Naukowe Uniwersytetu Jagiellońskiego" 1993, p. 43; L. Gruszow, *Ochrona wynalazków w dziedzinie biotechnologii według Konwencji o patencie europejskim,* „Zeszyty Naukowe Uniwersytetu Jagiellońskiego" 1990, issue. 52, pp. 17–18.

[20] I.e. Journal of Laws of 2017 r., item 776.

ordinary discovery of one of its elements, including the sequence or a partial sequence of a gene.

The conclusion is that the issue of biotechnological inventions is primarily connected with the questions concerning the axiological sphere. The main objective of the legislation on biotechnology is providing an adequate level of protection in the field of the process of biotechnology as well as the safe transfer of knowledge, handling, and using of a modified living organism. This is because biotechnology may lead to grave consequences for the development of a human being. The application of biotechnology requires appropriate safety measures for protecting the safety of life and human dignity.

In the area of science, new technologies are constantly confronted with the protection of personal interests. However, the discussed question does not refer only to a problem of an individual but constitutes an issue that would require a broad debate on the future of a man and all humanity. A vast area of essential regulations connected with the development of technologies allows us to deal with these issues very selectively, choosing the most problematic issues associated with protecting human dignity and human life. The analysis of the evolution of new technologies and their impact on the development of an individual and the state is necessary for understanding the whole issue. This requirement refers to all matters connected with the regulation of new technologies and the process of their functions in the era of new technologies. It should be emphasized that at the foundations of techne, one can always find human activity. It is precisely the same as with the principles of every legal system where there are present human needs for organizing and putting in order things and the world. Nowadays, most systems work based on complicated algorithms; however, the foundation of their activities must be thoroughly based on a crucial value of human life and dignity.

The development of computers and digital techniques creates new needs for an individual and society. For fulfilling them, the science, to unbelievably great scale, allows breaking time and space boundaries. New legal regulation enters new areas accompanying the development of technology.

It should be mentioned that the legal system includes the norms of general and legal structure, which should be expressed in the contents of a legal act and are logical and axiological justification or consequence of the norms expressed in the normative texts. So that is why it is essential to determine the axiological foundations of specific regulations and their consequences resulting from logical deductions. It seems that it is a necessary stage in the regulatory process of the new areas of science. In this way, it is indispensable to appeal to the foundations of the regulations expressed in the Constitution of the Republic of Poland, simultaneously – because of being the Member State – bearing in mind the foundations of the regulations present in the European law or international contracts. Frequently, the axiology which we seek may be varied in different legal systems, and getting to know the essence of a given legal issue may constitute some difficulties connected with a global character of their economies, which stimulate the development of science and scientific research. However, following the primary goal of these legal activities, which aim at establishing and protecting the fundamental values covered in the system of regulation of new technologies and

functioning of an individual in new technologies, it is necessary to re-define the public interest aims. The "network" state requires the re-definition of its tasks.

Cyberspace is currently the central area of human activity. This refers to economic exchange, to the exchange of various types of contents, thoughts, ideas, views. Thus, the most crucial arising question of this analysis is the issue of the boundaries of the development and the impact of new technologies as a result of scientific research. On the one hand, new technologies determine the development, but they may be restricted by the law, e.g., the ownership law (patent law). On the other hand, the innovations contribute to the interference of these rights, making their protection weaker. In each of these situations, we have to face a threat to the sense of security of an individual, of the society, and the whole of mankind. In the case of inventiveness, special consideration should be given to moral and ethical issues referring to the regulations of genetic engineering in the situation in which the latter is very advanced. The human body is becoming to some extent – nowadays still limited – excluded from the natural order and is becoming a commodity, an object of trade. That is why in the context of the debate on the justification of the science and the content which defies the universally accepted system of values, human dignity, and all the laws consequently protecting it, arrangements referring to the issues of human life are the essential elements of the future regulations.

These issues touch on the very delicate questions of interfering from the earthly order into human nature. In this subject of legal regulation, one should always seek answers to questions about acceptable boundaries of the interference of technology in human life.

Summary

These issues touch on the very delicate questions of interfering from the earthly order into human nature. In this subject of legal regulation, one should always seek answers to questions about acceptable boundaries of the interference of technology in human life.

Key words: Ethics and law in biotechnological inventiveness, human genetic engineering

Etyka i prawo w wynalazczości biotechnologicznej na przykładzie inżynierii genetycznej człowieka

Streszczenie

Zagadnienia te dotykają bardzo delikatnych kwestii ingerencji świata fizycznego w ludzką naturę. W tak ujętej regulacji prawnej należy zawsze szukać odpowiedzi na pytania o dopuszczalne granice ingerencji technologii w życie człowieka.

Słowa kluczowe: etyka i prawo w wynalazczości biotechnologicznej, inżynieria genetyczna człowieka