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Legal aspects of human cloning under international regulations

Prawne aspekty klonowania ludzi w perspektywie regulacji międzynarodowych

Introduction

At the beginning of 2018, the world was spreading news about the first successful cloning of macaques by Chinese scientists¹. It was the first case of cloning of primates and it gave rise to a discussion, previously suspended for many years, about hypothetical consequences and dangers resulting from human cloning. For the first time since the famous case of cloning *Dolly* sheep, a birth of which in 1996 in Scotland touched international public, such remarkable progress in this field has been made. The current science achievements indicate that finding technology which would fully enable to perform such procedure, is only a question of time.

From the technical point of view, human cloning means artificial creation of genetically identical copy (a clone) from somatic cell of the donor. In other words, it is obtaining a new organism with genetic material identical with the original (“starting”)² one. The basic genetic information in case of all living beings is included within the structure of deoxyribonucleic acid (DNA), i.e. genome³. It is worth adding, that multiplying embryos within the process of artificial insemination (*in vitro*) is also a kind of cloning. *In vitro*, however, concerns only reproductive cells, which makes the weight of discussion regarding

¹ Z. Liu, Y. Cai... *Cloning of Macaque Monkeys by Somatic Cell Nuclear Transfer*, Cell, Volume 172, Issue 4, p. 881–887, 08.02.2018.

² T. Twardowski, A. Michalska, *Problemy etyczne i prawne klonowania*, Ruch Prawniczy, Ekonomiczny i Socjologiczny nr 62 (4/2000), p. 1- 18.

³ *Ibidem*. p. 1- 2.

cloning placed mostly over process of cloning with the usage of somatic cells (for example: hair, skin, nails)⁴.

Typically, two kinds of cloning are distinguished: therapeutic cloning and reproductive cloning⁵. The first one means cloning of human cells and tissues for therapeutic and transplantation purposes and nowadays it enjoys the interest of numerous scientific and research centres, however, in none of the countries it is already functioning in medical practice. As examples of the most popular therapeutic methods shall be mentioned so-called SCNT - somatic cell nuclear transfer and so-called iPSC - induced pluripotent stem cells⁶. As closely linked to therapeutic cloning we can also note so-called cell-stem research⁷. The second, much more controversial one, type of cloning is so-called „reproductive cloning”. It does not limit only to multiplying cells and specific tissues, but the main purpose of it is to achieve brand new and independent organism, having DNA code identical to its donor⁸.

The discussed technology, provided that used responsibly, in opinion of many can remarkably contribute to the fastest medicine development in history, help in curing numerous genetic diseases and more and more common infertility of couples.

On the other hand, it is exceptionally controversial not only from the religious or bioethical point of view, and having many opponents. The process of cloning definitely poses a risk of severe health complications both for the women carrying the clone and for the cloned persons themselves. It is a result of multiple factors – amongst others, the fact that the starting material is constituted of already mature and often very vulnerable to various mutations somatic cells. Taking into consideration high risk for health and life of animals in the process of their cloning, similar attempts taken towards humans would be dangerous, irresponsible, and therefore, highly unethical⁹.

⁴ *Ibidem*, p. 1- 2.

⁵ F. Bowring, *Therapeutic and reproductive cloning: A critique*. Social Science and Medicine, 2004, Vol. 58 (2): 401– 409.

⁶ Ching-Pou Shih, *Moral and Legal Issues Concerning Contemporary Human Cloning Technology: Quest for Regulatory Consensus in the International Community to Safeguard Rights and Liberties Essential to the Future of Humanity*, Golden Gate University School of Law: Theses and Dissertations, 2010, p. 26- 30.

⁷ *Ibidem*, p. 26- 31.

⁸ T. Twardowski, A. Michalska, *Problemy etyczne...* p. 2.

⁹ I. Wilmut, *The limits of cloning*. New Perspectives, Vol. 31 (1): 38– 42.

Naturally, there is also suspicion that such „playing God” contradictive to the nature affects the dignity and respect for human – both for cloned and genetic donor, through treating human’s life as an object and normalization of experiments on humans and human embryos¹⁰. There is also mentioned a couple of dangers arising under the misuse of this technology against societies’ integrity and the public security. It is also worth noting about possible pathologies and perversions of nature, such as appearance of „clones cultures” in order to use their organs and tissues as spare parts, or creation of black market of human embryos trafficking, having for example specific and desirable genetic features¹¹.

Also from the society’s perspective, so-called „reduction of the gene pool” can directly lead to decreased immunity, and therefore to expose humanity to various pandemics to the unprecedented extent.

Overly complex nature of the concerned issue can be also noted to legal perspective thereof. One can imagine numerous potential problems which could arise even in such fields as human rights (the conflict of human dignity on one hand, and procreation rights on the other). Also in the context of family law (in particular parental rights and maintenance obligation) the „parents” of the cloned child shall be legally identified from the range of potential candidates such as donor of the genetic material, its heirs, and possibly even the doctor, if he/she conducted the process of cloning in “authorized” manner. The conclusion of those issues will be obviously crucial for the law of succession. Numerous potential doubts are based also in such fields as intellectual property law – for example, patent law. The same applies to questions such as privacy or publicity rights (it is enough to imagine a clone of renowned authority or celebrity used for public and commercial purposes). There is also problem of rights of original genetic material owner and claims of person, the DNA of whom has been used to production for example a series of clones. The dissemination of cloning technology would also result in the urgent need of adjustment of public law to (i.e. in the scope of genetic diversity and biodiversity preservation), and penal law norms (effective prevention of illegal practices such as embryos trading or human/human organs trafficking).

The importance of the issue of human cloning requires decisive actions on the part of the specific state’s legislators. The problem cannot be considered as solved by the fact that until the year of 2018 almost 80 countries have internal regulations – more or less restrictive ones – concerning human cloning

¹⁰ Ching- Pou Shih, *Moral and Legal Issues...* p. 65- 78.

¹¹ J. Bernard, *Od biologii do etyki*, Warszawa 1997, Wyd. Naukowe PWN, p. 190- 193.

prohibition¹². Leaving even a couple of blank spaces on legislative map of the world can result in mass phenomenon of searching liberal legal systems by the research teams (so-called „venue shopping”), and thus, consequences for all international community¹³.

Moreover, there shall be made legal differentiation between the reproductive cloning and therapeutic cloning – considered in science as showing a great potential for the development of medicine, and characterized by lack of the most of concerned dangers. An equal treatment of both types of cloning has been for years a reason of not involving fully the great potential which lies in the development of so-called cell-stem research, which, due to their reproductive character, are considered as timeless breakthrough in the field of transplantation.

In the international doctrine there has been for years underlined an urgent need for achieving trans-national unity and homogenisation in the scope of the legal approach to the question of cloning. The basis for such approach was a conviction that the adverse effect of the lack thereof in a natural way will go beyond of the specific countries’ borders and their legislative systems. In order to estimate the scale of the problem, it is therefore worth closely analyzing the actions taken up-to-date and the current legal situation regarding cloning under international public law.

Patent law and human cloning

Firstly, it shall be considered whether patent law provides certain protections against human cloning. It results from the fact that the creation of the concerned technology, which requires considerable financial commitments, would turn out to be unprofitable in case where it is not possible to obtaining of a patent.

Under international patent law, the problem of cloning find its basis indirectly in art. 27 section 2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)¹⁴ and art. 53 of the Paris convention¹⁵, pursuant to which the patent protection can be dismissed due to protection of public interest, protection of morality, protection of health and life of people, and also the danger caused to natural environment. The Polish act on industrial property law refers

¹² <https://www.geneticsandsociety.org/topics/human-cloning>.

¹³ Ching- Pou Shih, *Moral and Legal Issues...* p. 216.

¹⁴ <http://eur-lex.europa.eu/legal-content/PL/TXT/?uri=LEGISSUM:r11013>.

¹⁵ Paris convention on industrial property protection dated 20 March 1883 r., J.L. 1975. No. 9, item 51.

to the above in art. 29 section 1 point 1. Pursuant thereto, the patents are not granted to inventions the usage of which would be contrary to the public interest or decency, in the same time the usage shall not be classified as contrary to the public interest or good will solely on the basis of the usage prohibited by law¹⁶.

Already under those regulations there would be, therefore, possibility to dismiss granting of a patent for invention of human cloning technology, the usage of which would be contrary to public interest. Both conventions are of crucial importance due to their common character – they have been applied by, accordingly, 162 and 177 countries.

Solution similar to those based on conventions is functioning also under art. 53 of European Patent Convention (Convention on the Grant of European Patents). However, the most strict legal rules are based in European Union upon the directive 98/44/WE, pursuant to which the methods of human cloning (including the technology of embryo division, aimed at creation of human with the same cell genetic information as other human's) shall be deemed as contrary to public morality and, therefore, the granting of patent is dismissed. This means the definitive prohibition of granting patent to method of human cloning within the European Union. Implementation of this provision in Poland is reflected by art. 93(3) section 2 of Polish industrial property law¹⁷.

The granting of patent to human cloning method does not seem possible also in other jurisdictions. For example, also in the United States the developments in research concerning human cloning have been stopped by the proper interpretation of patent law. However in the US there does not exist any provision directly prohibiting granting of patents to inventions contrary to public decency or interest, the judiciary has successfully formed a range of patent exclusions. Pursuant to the art. 101 of US Federal Patent Act, the patentable inventions shall be new, useful and unobvious. It is considered, however, that products of nature cannot be subject to patent due to fact of not meeting the obligations above – in particular the requirement of new character (*Funk Bros Co v. Kalo Inoculant Co*¹⁸ and *Diamond v Dieker* cases¹⁹). Another reason is the reasoning presented by the United States Patent and Trademark Office, which officially deems human cloning as contrary to the 13th Amendment to Constitution, prohibiting slavery and compulsory serving other people. One also brings an

¹⁶ P. Kostański, Ł. Żelechowski, *Prawo własności przemysłowej*, C. H. Beck Warszawa 2014, p. 71.

¹⁷ Polish Act of 30 June 2009 – Industrial Property Law, J.L. 2001 no. 49 item 508.

¹⁸ *Funk Bros Co v. Kalo Inoculant* 333 US 127 (1948).

¹⁹ *Diamond v Dieker* 450 US 175 (1981).

argument that granting of patent to human cloning would be contrary to the 14th Amendment which guarantees the right to reproduction. In turn, in the recent „*Roslin Institute*” case dated 8 May 2014 the federal court dismissed application for granting of patent to mammals cloning method which has been used for obtaining *Dolly* sheep, due to the fact that the cloned creature has been an ideal copy of the natural phenomenon, not meeting therefore the requirement of the new character under art. 101.

The obstacles above do not mean, however, that such invention as reproductive cloning method cannot be used. There shall be therefore acknowledged a dangerous character of situation in which the actual threshold for cloning is exclusively patent law, and there shall be searched other barriers for the development of such technology on the international level.

1. Norms of international law

1.1. The Council of Europe

First steps of the members of the Council of Europe facing challenges started by the development of technology date back to 1982. In recommendation no. 934 of the Parliamentary Assembly regarding genetic engineering there was included opinion that right to life and human dignity (preserved by articles 2 and 3 of the European Convention on Human Rights) shall be also concerned as right to succession of genetic structure, which has not been “artificially modified”²⁰. In turn, in recommendation no. 1046 (dated 1986) the Parliamentary Assembly called the member countries to introduce prohibition of creating the human embryos by manner of in vitro insemination for scientific purposes. Moreover, the recommendation addresses negatively the issue of creation of human beings with the usage of any method – including cloning²¹. Another step taken by the Council of Europe was resolving in 1997 the Declaration of the Council of Europe concerning the prohibition of human cloning²². Despite the fact that this document does not have a binding character, a key importance had

²⁰ T. Twardowski, A. Michalska, *Kontrowersje- Klonowanie*, Medycyna Wieku Rozwojowego (5/2001), p. 187.

²¹ *Ibidem*.

²² C. Mik, *Klonowanie człowieka w pracach Unii Europejskiej*, Medycyna Wieku Rozwojowego, 2001, Suplement 1 do nr 1, p. 206.

the admission that “cloning poses a serious threat” and the Member Countries shall „take any and all steps in order to prohibit human cloning”²³.

A breakthrough initiative of the Council of Europe turned out to be The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine²⁴ (also known as “European Bioethical Convention” or the “Oviedo Convention”). The convention is first international treaty protecting the integrity of human existence, and in the same time an instrument demonstrating the determination of the Council of Europe in striving for taking control over potential threats arising from the development of biomedicine²⁵. It puts emphasis on the need of common respect to human life both in its individual and collective aspect, expressly prohibiting the creation of human embryos for scientific purposes. As to date, the Convention has been ratified by 29 Countries²⁶.

A main idea thereof, expressing the aim of protecting human beings from the instrument approach and consequences of the development of biomedicine, has been included within the article 2:

Article 2 (Primacy of the human being)

The interests and welfare of the human being shall prevail over the sole interest of society or science.

And the issues regarding indirectly human cloning have been included within articles 13 and 18:

Article 13 (Interventions on the human genome)

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

Article 18 (Research on embryos in vitro)

1. *Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.*
2. The creation of human embryos for research purposes is prohibited.

²³ Ching- Pou Shih, *Moral and Legal Issues...* p. 208.

²⁴ Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*, English language version available for example at <https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164>, Polish language version available for example at T. Jasudowicz, *Europejskie standardy Bioetyczne. Dokumenty i Orzecznictwo*, Kraków 2014.

²⁵ R. Andorno, *The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law*, *Journal of International Business Law* Vol. 02, 2005.

²⁶ Ching- Pou Shih, *Moral and Legal Issues...* p. 209.

The purpose of the Convention was to achieve international (and as wide as possible) consensus, which was possible exclusively thanks to providing only such low and minimal level of protection in the Convention. It resulted from the significant differences in views and principles between the countries of catholic tradition, and on the other hand the states in which a strong impact is put on the development of human embryos cloning technology (in particular in the scope of cell-stem research). Therefore, there is no direct reference to the problem of human cloning.

In 1998, due to too general wording of the Convention, an Additional Protocol regarding prohibition of human cloning has been resolved²⁷, which raised protection standard and became first legally binding document of an international character, directly addressing the issue of human cloning.

The Preamble of the Protocol indicates two crucial motives which have been taken into consideration when adopting it. These include: science development in the scope of mammals cloning and the fact that human cloning can be possible in the nearest future²⁸. From the Preamble it results also that any form of cloning aiming at obtaining genetically identical human being is contrary to human dignity and shall be classified as inappropriate usage of biology and medicine.

The most important provisions of the Protocol have been included in first two articles:

Article 1

Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.

Article 2

No derogation from the provisions of this Protocol shall be made under Article 26, paragraph 1, of the Convention.

Within the meaning of the article 1, the notion of human being „genetically identical” to other human being means a human being sharing with the other one the same set of genes included in the cell nucleus. Article 2 however expressly exempts the possibility of applying the exceptions from the Article 26.1 of the Convention (permitting to exclude rights and guarantees in case of the need of

²⁷ Council of Europe, *Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine on the Prohibition of Cloning Human Beings*, English language version available for example at <https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/168>, Polish language version available at T. Jasudowicz, *Europejskie standardy Bioetyczne. Dokumenty i Orzecznictwo*, Kraków 2014.

²⁸ T. Twardowski, A. Michalska, *Kontrowersje- Klonowanie...* p. 187.

public interest protection, prevent crimes, public health protection or protection of rights and freedoms of other people).

The breakthrough nature of the Protocol is based on the fact that it explicitly prohibits human cloning. However, the natural consequence of the precisely characterizing the scope of this prohibition is the fact, that up-to-date it has been ratified only by 24 countries²⁹. As the „great absent” there shall be mentioned, amongst others, Germany, Great Britain, Russia and Poland (the latter, despite signing the Protocol in 1999, has not decided so far to ratify it due to the doubts regarding for example the level of human life protection towards the requirements provided under the Polish Constitution³⁰).

Pursuant to the official Explanatory Report to the Additional Protocol, the diversity and randomness of the genetic combination of the human determine its uniqueness and it shall not be used³¹. What is important, the Report mentions that the Protocol does not express any opinions as of ethical admissibility of the Osage of cells and tissues cloning method for the scientific purpose and medical usage, where this technique may be valuable³². There appears the conclusion that the Protocol prohibits only cloning for reproductive purposes, while leaving in a sole discretion of countries the question of regulating the problem of therapeutic cloning. In some countries the Convention is interpreted, however, in a more strict manner, which limits significantly also the domestic usage of the specific methods of therapeutic cloning³³.

2.2. The European Union

The first actions taken by the EU structures were two resolutions adopted in, accordingly, 15 January 1998³⁴ and 7 September 2000. In the first of those the

²⁹ https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/168/signatures?p_auth=nbBbePS6.

³⁰ J. Lipski, *Opinia prawna na temat zgodności z Konstytucją RP Konwencji Rady Europy o ochronie praw człowieka i godności istoty ludzkiej w odniesieniu do zastosowań biologii i medycyny*, Zeszyty Prawnicze Biura Analiz Sejmowych Kancelarii Sejmu, no. 2 (42), 2014.

³¹ *Council of Europe, Explanatory Report to the Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings*, English language version available for example at <https://rm.coe.int/16800ccde9>.

³² <https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/168>.

³³ https://cnx.org/contents/4O_mfmxO@1/Overview-of-World-Human-Cloning.

³⁴ Rezolucja Parlamentu Europejskiego w sprawie etycznych i prawnych problemów inżynierii genetycznej.

European Parliament called to prohibit human cloning and to ratify the European Convention on Bioethics together with the Additional Protocol. In the second one it expressed, in turn, an opinion that therapeutic cloning consisting of creating human embryos exclusively for scientific purposes is contrary to the European Union's Policy. Despite its non-binding character, both resolutions have made certain impact on the law of specific countries, designating a defined protective trend in this field.

The greatest achievement within the EU was adopting the Charter of Fundamental Rights of the European Union³⁵ (taking its standards from the European Convention on Human Rights) in 2000, which together with ratifying the Treaty of Lisbon from 2007 has become legally binding both for EU institutions and the specific Member Countries. .

The provisions regarding human cloning have been included in title I (Dignity), in articles 1 and 3:

Article 1

Human dignity

Human dignity is inviolable. It must be respected and protected.

Article 3

Right to the integrity of the person

1. Everyone has the right to respect for his or her physical and mental integrity.
2. In the fields of medicine and biology, the following must be respected in particular:
 - (d) the prohibition of the reproductive cloning of human beings.

The Charter of Fundamental Rights is the first document of such range, in which the term of „reproductive cloning” has been directly used in relation to human beings³⁶. Similarly to the solution applied in the European Bioethical Convention, the Charter on Fundamental Rights is characterized by completely neutral position in relation to therapeutic cloning. This approach has also its confirmation in the official Clarifications to the Charter of the Fundamental Rights of the European Union.

³⁵ *European Commission, EU Charter of Fundamental Rights*, English language version available for example at ec.europa.eu/justice/fundamental-rights/charter/index_en.htm, Polish language version available for example at T. Jasudowicz, *Europejskie standardy Bioetyczne. Dokumenty i Orzecznictwo*, Kraków 2014.

³⁶ *Official Journal (OJ.) of the European Communities*, C 346/1 (18 December 2000), English language version available for example at http://www.europarl.europa.eu/charter/pdf/text_en.pdf.

2.3 United Nations

At the global level the biggest number of attempts aiming at regulating the problem of human cloning and achieving homogenous international position within the United Nations and its subsidiary specialized agencies.

Beyond all, there shall be mentioned the activity of the World Health Organization and, organizationally, its most important body – the World Health Assembly. In 1997 and 1998 the WHA while taking into consideration the topic of human cloning, has adopted first two resolutions (WHA 50.37 and WHA 51.10) which stated that „reproductive cloning is unethical and contrary to the dignity and integrity of human being”³⁷.

Then, in 1999 there was conducted wide-range Consultations concerning the problems of genetics, cloning and biotechnology in order to elaborate further operations for the UN bodies. Further, in 2002 the WHO applied a distinct differentiation between reproductive cloning and cloning for medical research purposes, while calling to implement this differentiation also in the law of particular countries. Then, beginning from 2002, within the WHO a special department commenced functioning, dedicated to bioethical issues and aiming at developing further solutions to present them to UN General Assembly³⁸.

Another significant step in the activity of the UN was adopting in 1997 by the United Nations Educational, Scientific and Cultural Organization, and subsequently by the UN General Assembly, the Universal Declaration on the Human Genome and Human Rights (resolution 53/152)³⁹. The purpose thereof is protection the integrity of the human kind from being violated, from practices contrary to the rule of equal dignity and unfair usage of the scientific research results. Pursuant to the article 1, „*The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity*”⁴⁰. Pursuant to the article 2: „*That dignity makes it*

³⁷ Ching- Pou Shih, *Moral and Legal Issues...* p. 214.

³⁸ *Ibidem*.

³⁹ *Universal Declaration on the Human Genome and Human Rights*, resolved by the UNESCO General Conference on 11 November 1997, approved by the UN General Assembly by the Resolution 53/152 dated 10 December 1998; Polish language version available in T. Jasudowicz, *Europejskie standardy Bioetyczne. Dokumenty i Orzecznictwo, Kraków 2014.*; English language version available for example AT <http://www.unesco.org/ibc/uk/genome/project/index.html>.

⁴⁰ Polish version: *Powszechna Deklaracja o Genomie Ludzkim i Prawach Człowieka*, Wyd. Polski Komitet ds. UNESCO, Warszawa 1998; T. Twardowski, A. Michalska, *Kontrowersje- Klonowanie...*p. 189.

*imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity*⁴¹.

However, the biggest significance to the mentioned Declaration shall be attributed under the notable article 11, with the wording as follows:

Article 11

Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.

Thus, the Declaration was a first international law act condemning reproductive cloning, as contrary to human dignity. Despite the lack of binding character, the Declaration constituted a major progress, and also an important example of so-called soft law, indicating global trend and being inspiration for many states legislations. Also in this case due to political reasons there was not enough will for making any reference to the possibility of admissibility of therapeutic cloning. It results directly from the fact that within the UN the differences of opinions are even more visible, preventing from achieving more definitive solutions.

In connection with the lack of binding regulation definitively prohibiting reproductive human cloning in 2001 France and Germany presented first initiative of adopting international Convention which would change this state. The purpose of such actions was also to fulfill certain gaps in domestic legislations which leader to the already mentioned so-called „venue shopping”, so freedom of entities carrying out research over cloning to choose the countries characterized by the liberal norms in this scope. Also there has been made the proposition of regulating the research over stem cells in order to make them admissible in certain, strictly specified and justified cases.

The considerations over such convention made visible, however, a deep division into two camps of countries, a part of which expected liberalization and release resources of the UN for research (Germany, Great Britain), and the other one searched a possibility of extending the prohibition over any and all forms of human cloning (in particular: Spain, Italy, United States)⁴². As a result, the works on the convention were ceded to specialty appointed ad hoc committee,

⁴¹ Polish version: *Powszechna Deklaracja o Genomie Ludzkim i Prawach Człowieka*, Warszawa 1998, Wyd. Polski Komitet ds. UNESCO.

⁴² Ching- Pou Shih, *Moral and Legal Issues...* p. 216.

which works ended only in 2003 and did not effect in achieving the expected consensus⁴³.

The polarization of the political scene on the UN arena subsequently led to proposing two separate projects. The first one, made by Costa Rica, aimed at providing binding prohibition of all forms of cloning, including therapeutic cloning. The second one, on the initiative of Belgium, had the purpose of definitely prohibiting the reproductive cloning, simultaneously providing full discretion to the specific countries in the context of therapeutic cloning. In spite of numerous hidden attempts by both groups, none of the propositions acquired the majority and has been adopted by the UN General Assembly. In the meantime, also moderate proposition made by Honduras.

The breakthrough did not occur also in 2005 when the UN General Assembly adopted non-binding Declaration on the problem of human cloning⁴⁴, calling to provide complete prohibition of any and all forms of human cloning. By Declaration, “*The General Assembly hereby solemnly calls al. Member States to introduce a prohibition of All forms of human cloning to the extent they are contrary to human dignity and protection of human life*”.

In the voting there have been noted 84 votes „for” and 34 votes „against”, and 37 „abstained”. The Declaration has obtained wide support from catholic countries, however it has been strongly criticized by the states with already developed research programs over the usage of stem cells. In turn, numerous Islamic countries did not take part in the discussion⁴⁵.

Many conservative countries have expressed the concern that the prohibition of the reproductive cloning may result in alleged allowing to therapeutic cloning. In turn, the supporters of liberalization were not willing to agree on universal prohibition of any and all types of human cloning⁴⁶. It has effectively prevented from acquiring the consensus and led to final division. Some of the countries, including China, Belgium and Great Britain have expressly declared that they have no intention of meeting obligation provided thereunder. Many countries also expressed their deep disappointed of the lack of consensus in the problem

⁴³ *Ibidem*.

⁴⁴ United Nations Declaration on Human Cloning (2015), Polish language Mersin available in T. Jasudowicz, *Europejskie standardy Bioetyczne. Dokumenty i Orzecznictwo, Kraków 2014.*; English language version available for example at <https://digitallibrary.un.org/record/541409>.

⁴⁵ https://en.wikipedia.org/wiki/Human_cloning#cite_note-PoloHorses-44.

⁴⁶ A. Langlois, *The global governance of human cloning: the case of UNESCO*, Palgrave Communications, 2017, DOI: 10.1057/palcomms.2017.19, p. 3.

concerned, and abandoning by the UN of the project of differentiating between two forms of cloning, with the separated approach to cell-stem research⁴⁷.

Despite numerous appraisal voices on the part of Declaration's supporters in its current, critical towards cloning (including therapeutic one) form, it has become definitely weakened and unclear instrument to lead to a real change in the politics regarding human cloning⁴⁸. In my opinion, the Declaration shall be considered as a failure for at least 4 reasons. Firstly, the Declaration does not have binding character, despite the fact that works conducted for many years were in their assumptions lead to adopting the binding international treaty. Secondly, the original authorization to the Legal Committee regarded the project opposing only the reproductive cloning. Thirdly, the wording of the Declaration is very general, calling the member countries only to prohibit cloning „*in the scope of being contrary to human dignity and protection of human life*”. It can be, however, assumed in advance, that actions of any nature contrary to the values above should be subject to general delegalisation. Fourthly, the Declaration has been adopted by unclear majority and in the circumstances which deprives it even of moral authorization towards specific countries. On the contrary – instead of setting international trends in the approach to human cloning, it has showed the profound division between the UN members, thus resulting in the making the tabor from the problem of cloning in the UN arena and depriving for years of the hope of regulating those issues appropriately.

The expected results have not been also brought by the organizations affiliated by the UN: International Bioethics Committee and Intergovernmental Bioethics Committee⁴⁹. Although the Working Party on human cloning appointed in 2008⁵⁰ recommended the need of adopting by the UN General Assembly of the international convention prohibiting human cloning⁵¹, but due to the previous circumstances of the political nature, the issue has not been discussed in a plenary session⁵². The works within the following Working Programme operating on behalf of the IBC and IGBC in 2010- 2011 have been ended up with the conclusion that despite the need of regulating the issue of cloning, in

⁴⁷ Ibidem, p. 3- 4.

⁴⁸ United Nations University Institute of Advanced Studies. (2007) *Is Human Reproductive Cloning Inevitable: Future Options for UN Governance*. UNUIAS: Pacifico-Yokohama, Japan.

⁴⁹ A. Langlois, *The global governance...* p. 3- 6.

⁵⁰ UNESCO, *First Meeting of the Working Group of IBC and First Public Hearings on Human Cloning and International Governance*.

⁵¹ UNESCO: *Report of the Working Group of IBC on Human Cloning and International Governance*.

⁵² A. Langlois, *The global governance...* p. 4.

this regard there are still political obstacles impossible to fight⁵³. The issue of cloning has been again undertaken only Turing the next Working Programme in 2014- 2015, and it has been summed up by the Report⁵⁴, which, as facing the longstanding dispute in the plenary sessions of the UN, indicated the urgent need of authorizing the specialized UN agencies (including UNESCO) to take the appropriate normative steps⁵⁵.

In the context of considerations on legal aspects of cloning there shall be, in my opinion, particularly concerned that the last Working Programme of IBC for the years of 2016-2017 did not include in its agenda the problem of human cloning at all⁵⁶.

It is worth adding the actions of G8 Group (Canada, France, Germany, Japan, Russia, Great Britain and United States), which during 23th G8 Summit in Denver urged to prohibit reproductive human cloning⁵⁷.

Lack of international legal framework – especially of general character – results nowadays in the exceptional normative chaos showed by wide range and discrepancies between the specific domestic regulations. In 2018, pursuant to the Center for Genetics and Society 46 countries prohibit any and all forms of human cloning, and another 32 states prohibited only the reproductive cloning, while leaving an opportunity for the research teams in order to clone cells and tissues and embryonic stem cells⁵⁸. An excellent illustration of „legislative schizophrenia” in that area is the United States, where only a couple of states ban reproductive cloning and several others prohibit only financing such from public funds. What is more, the legal systems of many countries are characterized by far-reaching defectiveness and not being up to date. Amongst countries prohibiting cloning many regulations refer directly to SCNT method, which de facto makes them inapplicable to the other, especially the newest technologies⁵⁹.

⁵³ UNESCO: Human cloning and international governance, www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/internationalbioethics-committee/ibc-sessions/seventeenth-session-paris-2010/.

⁵⁴ UNESCO: Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights.

⁵⁵ A. Langlois, *The global governance...* p. 5.

⁵⁶ Preliminary Work Programme of the IBC for 2016-2017, www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/internationalbioethics-committee/work-programme-for-2016-2017/.

⁵⁷ Communiqué of Group 8 Denver Summit(1997), English language version available for example at: <http://www.g8.utoronto.ca/summit/1997denver/index.htm>.

⁵⁸ <https://futurism.com/human-cloning-whats-stopping/>.

⁵⁹ Lo B et al (2010), *Cloning mice and men: Prohibiting the use of iPS cells for human reproductive cloning*. *Cell Stem Cell*; 6 (1): 16– 20.

3. Abstract

The progress in biomedical sciences indicates that appearance of technology permitting to clone human is only a question of time. What is more, within less than a decade, it might be in the reach of almost every good equipped laboratory. This vision create numerous problems not only from the perspective of health and security of people, but also controversies of moral, ethical and legal nature.

It is undeniable that taking legislative initiative on international level is needed due to the fact that the consequences of abuse in the face of usage of human cloning technology will have global effects.

The overview of existing norms of international public law indicate that there are two basic grounds of problems. The first of them results from the fact that part of provisions of the European Biomedical Convention and the Additional Protocol or the Chart of General Rights of the EU (binding more than 30 states) there does not exist as for now any law, which would prohibit human cloning for strictly reproductive purposes. In turn, the most rigorous as of wording the Declaration of the UN General Assembly is of, at most, pinion-forming character, especially taking into consideration a common criticism against it.

The second serious omission on the part of international society is the question of strictly protective approach to the problem of therapeutic cloning. In none of the documents of an international range there was included a direct admission of the usage of human cells and tissues for scientific and therapeutic purposes, taking up (in best case) neutral position (the Bioethical Convention, the Protocol, the Chart on General Rights). The permanent state of legislative suspension, and also the lack of recognizing of the great importance of such action for the science prevent from their financing, not only on the part of international organizations and specialized agencies thereof, but also by private entities – it results, amongst others, from the negative vibe surrounding this field and the natural fear of its immediate delegalisation (the high capital intensity together with the postponed rate of return effectively deters the investors).

Thus, the current legislative deadlock definitely blocks research over the usage of stem cells in medicine and transplantation which shall obtain a definitely negative opinion.

In order to meet the mentioned challenges of modern biotechnology and medicine there is an urgent need of adopting common, international Convention, which on one hand would prohibit cloning for reproductive purposes, and on the other hand introduce a strict differentiation between the specific types

of cloning, allowing for the development of therapeutic cloning and cell-stem research to be financed from public funds.

And despite the fact that in the field of biomedicine a characteristic phenomenon is that law has to considerably catch up with the development of science⁶⁰, there should still be hoped that the global policymakers take the appropriate steps, before the first successful case of human cloning will make the headlines.

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⁶⁰ M. Safjan, *Prawo i medycyna*, Warszawa 1998, Oficyna Naukowa, p. 10 - 11.

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Streszczenie

Na początku 2018 roku świat obiegrała wiadomość o pierwszym udanym klonowaniu makaków przez chińskich naukowców. Wszystko wskazuje na to, że uzyskanie technologii wystarczającej do pomyślnego sklonowania człowieka jest tylko kwestią czasu. Kwestia klonowania podlega jednak nie tylko kwestiom etycznym, ale także różnym ważnym kwestiom prawnym, w tym prawom człowieka, aspektom prawa rodzinnego (takim jak władza rodzicielska czy kwestie alimentacyjne) oraz prawu własności intelektualnej (np. prawo patentowe). W ramach każdego z tych zagadnień pojawiają się liczne kontrowersje prawne wymagające szczegółowej analizy dogmatycznej. Omawiając dylemat klonowania, należy pamiętać, że ostateczne konsekwencje niespójnego prawodawstwa dotyczącego klonowania niewątpliwie będą miały charakter ponadnarodowy, więc może należy ponownie rozważyć, czy potrzebna jest uniwersalna polityka i międzynarodowy konsensus, wykraczająca poza niewiążące deklaracje. Celem tego artykułu jest przedstawienie problemu klonowania ludzi z prawnego punktu widzenia, przeanalizowanie międzynarodowych polityk i regulacji przeciwko takim praktykom oraz wreszcie uchwycenie ogólnej tendencji i kierunku, w jakim zmierzają międzynarodowe przepisy w tej dziedzinie.

SŁOWA KLUCZE: klonowanie ludzi, regulacje międzynarodowe

Summary

At the beginning of 2018, the world was spreading news about the first successful cloning of macaques by Chinese scientists. Everything points to the fact that getting technology sufficient to successfully clone a human being is only a matter of time. However, the concept of cloning is subject not only to ethical questions but also to various important legal issues, including human rights, some particular aspects of family law (such as parental authority and child support regulations) and intellectual property law (patent law). As part of each of these issues, there are numerous legal controversies that require a detailed dogmatic analysis. While discussing the dilemma of cloning, it must be remembered that the final consequences of inconsistent cloning legislation will undoubtedly have a transnational character, so maybe it needs to be reconsidered whether a universal policy and international consensus on the matter is needed, going beyond the current non-binding declarations. The aim of this article is to present the problem of human cloning from the legal standpoint, analyze international policies and regulations against such practices and finally, to capture the general tendency and direction in which international legislation in this area is heading.

KEY WORDS: human cloning, international regulations

Autor

Łukasz Chyla - doktorant WPIA UJ pod opieką Prof. Andrzeja Szumańskiego, absolwent Melbourne Law School oraz Bucerius Law School w Hamburgu, a także Szkoły Prawa Amerykańskiego Columbus Law School. Do głównych zainteresowań naukowych należy prawo rynków kapitałowych, prawo międzynarodowe prywatne i arbitraż handlowy.