Legal Limitations on Genetic Research and the Commercialisation of its Results

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Introduction

Freedom of research is the underlining principle of any scientific activity. It has been restated in many international and national legal instruments. Thus, Article 15 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of 1997 (hereinafter: the Convention on Human Rights and Biomedicine), lays down the general rule:

Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.

The Convention on Human Rights and Biomedicine and its Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings of 1998 (hereinafter: the Protocol on the Prohibition of Cloning Human Beings) are in force in the Republic of Croatia since 1 March 2004.[1] In accordance with Article 140 of the Croatian Constitution, the Convention and the Protocol are now part of the Croatia's internal legal order, and are hierarchically positioned immediately below the Constitution and higher than other legal norms.[2] The principle of the freedom of scientific research has been advanced into a constitutional one in the Republic of Croatia. The Croatian Constitution also guarantees the material intellectual property rights protection over the results of research, which of course entail commercial exploitation of these results under the conditions provided by the law. The relevant part of Article 68 of the Constitution of the Republic of Croatia reads as follows:

Freedom of scientific, cultural and artistic creativity shall be guaranteed.
The state shall stimulate and assist the development of science, culture and the arts.
The state shall protect scientific, cultural and artistic goods as spiritual national values.
Protection of moral and material rights deriving from scientific, cultural, artistic, intellectual and other creative endeavour shall be guaranteed.

It goes without saying that this freedom is not unlimited. Article 16 of the Constitution provides for a leeway to limit basic rights and freedoms, which has to be justified on the basis of protection of rights and freedoms of others, legal order, public morality or health, and has to be in proportion to the need for any such limitation. Pursuant to the Constitution, the limitations, including those related to genetic research and to the commercialisation of its result, are introduced by means of provisions contained in the acts passed by the Croatian Parliament. Besides international conventions and legislative instruments, other methods are used for

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1 The Republic of Croatia signed the Convention and the Protocol on 7 May 1999, and they were ratified by the Croatian Parliament on 28 July 2003. The information on the Chart of signatures and ratifications of the Convention is available at: http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=04/02/2006&CL=ENG (last visited on 10 February 2006). See also the Act on Confirmation of the Convention On Human Rights And Biomedicine, 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, and the Additional Protocol To The Convention On Human Rights And Biomedicine Concerning Transplantation Of Organs And Tissues Of Human Origin, Official Gazette of the Republic of Croatia (hereinafter: OG RC) No. 13/2003.

2 Article 140 of the Constitution of the Republic of Croatia, OG RC No. 41/2001 (consolidated version), reads: "International agreements concluded and ratified in accordance with the Constitution and made public, and which are in force, shall be part of the internal legal order of the Republic of Croatia and shall be above law in terms of legal effects. Their provisions may be changed or repealed only under conditions and in the way specified therein or in accordance with the general rules of international law."

the purpose of regulating the sphere of biotechnology and related areas, such as ethical codes.

This Report seeks to identify the instruments in force in the Croatian legal system that impose restrictions over the genetic research related to humans, and commercialisation of the products of that research. It also intends to show that mounting concerns over this, by and large underregulated area, are not at all unjustified and that there is a critical need to adopt legislation to remedy this potentially hazardous situation.

Restrictions to Genetic Researc Related to Subject Matter of Research

This section of the Report examines the restrictions to genetic research depending on the subject matter of that research laid down in the Croatian law. Thus, specific comments are focused on the following four topics: cloning of human beings, stem cell research, eugenic practices and creation of chimeras and hybrids.

Cloning of human beings

Since the beginning of the 1950s, scientists have been more or less successful in cloning animals. The prospect of applying the same methodologies for the purpose of cloning human beings creates one of the most controversial issues in today's world.[3] Two major types of human embryo cloning have arisen hitherto: reproductive cloning and therapeutic cloning.

Reproductive cloning

In the Republic of Croatia, human reproductive cloning[4] is expressly prohibited by the provision of Article 97a of the Croatian Penal Act.[5] This Article prescribes that a person, acting with a goal of creating a human being that is genetically identical to another human being, shall be punished by imprisonment for at least six months and not more than five years. As further defined in Article 89, paragraph 34 of the Penal Act, the term human being "genetically identical" to another human being means a human being sharing with another the same nuclear gene set.

This prohibition was introduced into the Croatian Penal Act by the Act to Amend and Supplement the Penal Act of 15 July 2004 (hereinafter: the Penal Amendment Act 2004),[6] as a direct consequence of Croatia's ratification of the Convention on Human Rights and Biomedicine and the Protocol on the Prohibition of Cloning Human Beings.[7] Prior to the incorporation of Article 97a into the Penal Act, there were some discussions in Croatian legal circles whether the prohibition of human cloning should be regulated in the Penal Act, or in a separate act, which would also lay down the rules on artificial fertilisation techniques.[8] In the end, the first solution prevailed, most likely because the Penal Amendment Act 2004 was close to being prepared for enactment at the time the Convention on Human Rights and Biomedicine came into force in Croatia, so it was a much simpler and faster solution to insert an additional provision on human cloning into the Penal Act, than to wait

3 So far there have been several claims by "Clone-umbuses" of successful births of the cloned humans, but none of them has been scientifically proved. See *Best, Steven, Kellner, Douglas*, Biotechnology, Ethics, and the Politics of Cloning, in: Stehr, Nico (ed.), Biotechnology: Between Commerce and Society, Transaction Publishers, New Brunswick (USA)/London (UK), 2004, pp. 53-88, p. 65.

4 The term "human reproductive cloning", as used in this Report, means the creation of an embryo using somatic cell nuclear transfer, embryo splitting or any other technique with the aim of creating a genetically identical human being.

5 The Penal Act of the Republic of Croatia, OG RC, Nos. 110/97, 27/98, 50/00, 128/00, 51/01, 111/03, 190/03, 105/04, 84/05 and 71/06. Until July 2004, human reproductive cloning has also been prohibited in Argentina, Australia, Austria, Belgium, Brazil, Canada, China, Colombia, Denmark, Finland, France, Georgia, Germany, Greece, Iceland, Japan, Republic of Korea, Latvia, Mexico, the Netherlands, New Zealand, Norway, Peru, Portugal, Singapore, Slovakia, Spain, South Africa, Sweden, Switzerland, Thailand, United Kingdom and Vietnam. See National Legislation Concerning Human Reproductive and Therapeutic Cloning, UNESCO Division of the Ethics of Science and Technology, Paris, April 2004, available at unesdoc.unesco.org/images/0013/001342/134277e.pdf (last visited on 07 February 2006).

6 OG RC No. 105/04.

7 See Article 23 of the Convention on Human Rights and Biomedicine. It has been stated in the Croatian penal law scholarship that, by criminalising cloning of human beings, Croatia has fulfilled a part of its obligations stemming from the Stabilization and Association Agreement with the European Communities and its Member States (the text in the English version (contained in the Annex of the respective Proposal of a Council Decision, Brussels, 09.07.2001, COM(2001) 371 final, 2001/0149 (AVC)) is accessible at http://www.mvpei.hr/ei/download/2001/08/02/SAA CouncilProposal1.pdf (last visited on 29 May 2006)), to harmonise the Croatian penal legislation with the acquis communautaire. See *Basic, Franjo/Pavlovic, Sime*, Komentar kaznenog zakona, Organizator, Zagreb, 2004, p. 481.

8 See *Simonovic, Dubravka/Turkovic, Ksenija*, Pravna regulacija kloniranja u nas i u svijetu, Zbornik Pravnog fakulteta u Zagrebu, No. 6, Vol. 55, Zagreb, 2005, p. 1565.

until a separate act dealing with other aspects of genetic research and its results would be drafted.[9]

The title of Article 97a – "Prohibition of Cloning Human Beings" - and the description of this criminal offence, as well as the definition of the term "genetically identical human being" laid down in Article 89, paragraph 34, have been taken over verbatim from Article 1 of the Protocol on the Prohibition of Cloning Human Beings. As stated in the Explanation to the Draft of the Penal Amendment Act 2004, the raison d'être to enact Article 97a was to assure the protection of the dignity and the identity of all human beings,[10] a reason stated also in the Preamble of the Protocol.[11] Criminal law scholarship states that, considering the fact these values are protected by international instruments, the prohibition has not been placed in the proper section of the Penal Act. Instead of being included in the section titled "Criminal Offences against Life and Body", it should have been made part of the section "Criminal Offences against Values Protected by International Law".[12]

The examination of the actual provision of Article 97a reveals that conduct in violation of the prohibition does not amount to a criminal offence, unless the perpetrator is acting with dolus directus, in other words, with the direct intention of creating a genetically identical human being. At first glance, it would seem that therapeutic cloning is not caught by the prohibition, given that the goal of this technique is not creation of genetically identical human beings, but rather genetically identical human body parts. However, since therapeutic cloning entails a creation of an embryo, which is considered a human being by some and not by others, the accurate determination of the reach of the prohibition is necessarily dependant upon the legal definition of the notion of "human being".[13] Thus far the Croatian lawmaker has been reluctant to produce such a definition. Nonetheless, the conclusion that embryos are not legally considered human beings in Croatia can be drawn from the fact that pregnancies can be terminated in Croatia at will until the foetus is ten weeks old,[14] while at the same time the Croatian constitution proclaims that "every human being has a right to life".[15] In addition, the drafters of Article 97a expressly stated that this provision did not encompass any type of prohibition in respect to the manipulation or cloning of the cells or tissues for the purposes of medical research or for the therapeutic purposes.[16] Therefore, for the time being, Article 97a is to be interpreted restrictively to cover reproductive cloning only. Yet, the phraseology used in the provision leaves open a window for criminalizing therapeutic cloning either by defining a human being as such from an embryonic state for the purposes of the Penal Act, or by introducing a separate criminal offence pertaining to therapeutic cloning.

What also needs to be emphasized here is that the criminal offence is considered completed, i.e. the offence is deemed committed when the perpetrator has undertaken any action with the intention of creating a human clone.[17] As a consequence, the research directed at human reproductive cloning also falls under the scope of Article 97a of the Penal Act and is prohibited on the territory of the Republic of Croatia. However, when assessing

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9 The latter attempts to regulate other aspects of this issue see in infra section II.2.3.

10 See the Final Proposal of the Act to Amend and Supplement the Penal Act, Ministry of Judiciary, Zagreb, June, 2004, available at http://www.vlada.hr/Download/2004/07/08/31-04.htm (last visited on 10 February 2006).

11 The relevant Recital of the Preamble of the Protocol on the Prohibition of Cloning Human Beings reads: "Considering however that the instrumentalisation of human beings through the deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes a misuse of biology and medicine".

12 *Bacic/Pavlovic*, Komentar kaznenog zakona, op. cit., pp. 482-483; *Simonovic/Turkovic*, Pravna regulacija kloniranja u nas i u svijetu, op. cit., p.1566.

13 Here, it is important to emphasize that the Protocol on the Prohibition of Cloning Human Beings left it to domestic laws of member states to define the scope of the expression "human being". See Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings, available at http://conventions.coe.int/Treaty/EN/Reports/Html/168.htm (last visited on 12 February 2006).

14 See Article 15 of the Health Measures for Exercising the Right to Free Decision-Making on Procreation of Children Act from 1978, OG SFRY Nos. 18/1978, 31/1986 and 47/1989, OG RC No. 53/1991 (hereinafter: the Health Measures Act).

15 Article 21 of the Constitution of the Republic of Croatia.

16 See the Final Proposal of the Act to Amend and Supplement the Penal Act, Ministry of Judiciary, Zagreb, June 2004, available at http://www.vlada. hr/Download/2004/07/08/31-04.htm (last visited on 10 February 2006). A different situation exists in, for example, France, where both reproductive and therapeutic cloning have been labelled as criminal offences. See Articles 214-2, 511-18 and 511-18-1 of the French Penal Code, first sanctioning reproductive cloning, second banning cloning of embryos for research purposes, and third banning cloning of embryos for therapeutic purposes. The French Penal Code is accessible at http://www.legifrance.gouv.fr/WAspad/UnCode?code=CPENALLL.rcv (last visited on 30 May 2006).

17 *Bacic/Pavlovic*, Komentar kaznenog zakona, op. cit., p. 482.

whether the offence has been committed, criminal judges will have a difficult task in determining if the actual intent of the perpetrator was to create a human clone or not. This is because many procedures involved in human reproductive cloning are also used in other fields of genetic research.[18] Finally, the sanction for the act seeking to create genetically identical human beings (six months to five years of imprisonment) is rather lenient, when compared to sanctions prescribed in other legal systems.[19] Since the maximum term of imprisonment prescribed in the Croatian Penal Act is fifteen years, and in some cases even forty years,[20] it seems that the values which Article 97a of the Penal Act seeks to protect are positioned quite low on the scale of moral principles in the Croatian society.

Therapeutic cloning

Other than not being considered a criminal offence, the legal status of therapeutic cloning is not clear in the Republic of Croatia.[21] The problem lies in the fact that the Convention on Human Rights and Biomedicine, which is the only legal instrument applicable to matters of therapeutic cloning currently in force in Croatia,[22] precludes the creation of embryos for research purposes,[23] while at the same time it does not define the term "embryo", arguably leaving that issue to domestic laws of member states.[24] Given that such a definition does not exist in the Croatian law, it is not clear whether the prohibition laid down by Article 18, paragraph 2 of the Convention on Human Rights and Biomedicine

18 For example, somatic cell nuclear transfer, in which a nucleus from a cell of a particular person is inserted into an egg cell from which a nucleus has been removed, thus forming an embryo, is the initial stage of both reproductive cloning and therapeutic cloning.

19 In France, the perpetrators of this offence can be punished with thirty years of imprisonment and imposed a fine of 7,5 million Euros (Article 214-2 of the French Penal Code). In Italy sanction for the same offence ranges from five to ten years of imprisonment. See *Simonovic/Turkovic*, Pravna regulacija kloniranja u nas i u svijetu, op. cit., p. 1566.

20 To put this into the context, the minimum term of imprisonment in the Republic of Croatia is 30 days, while the maximum term is 15 years. There are two exceptions: first relates to the multiple crimes in the sense of Article 60 of the Penal Code when the maximum imprisonment term for all those crimes together may not exceed 20 years, and the other exception concerns committing the most sever and most dangerous forms of grave crimes when person may be convicted to 20-40 years imprisonment (Article 53, paragraphs 1 and 3 of the Penal Act).

21 The term "therapeutic cloning", as used in this Report, means the creation of an embryo using the somatic cell nuclear transfer technique with the aim of harvesting stem cells for subsequent tissue-culture amplification and injection into a host for therapeutic purposes. Currently, the only known technique with which therapeutic cloning could be achieved is somatic cell nuclear transfer, therefore the term therapeutic cloning as used in this Report encompasses only somatic cell nuclear transfer, while it is not excluded that therapeutic cloning shall be in the future possible utilizing new techniques.

22 While it is often true that acts regulating matters of artificial fertilization contain provisions that deal with issues relating to both reproductive and therapeutic cloning, the Health Measures Act neither explicitly nor implicitly touches upon this sensitive field of research. This is not surprising, since the Health Measures Act was adopted almost thirty years ago, when cloning was not considered technically feasible and still belonged to the sphere of science fiction. Disappointingly, the Health Measures Act was amended only concerning the fines prescribed for misdemeanours stemming from the violation of the Act; so it is now entirely unfit to bear with the occurring technological development in the field of human reproduction.

23 Until July 2004, creation of embryos for research purposes has been banned in Austria, Canada, Colombia, Denmark, France, Germany, Iceland, Japan, Norway, Peru, Slovakia, Spain, South Africa, Sweden and Switzerland. See National Legislation Concerning Human Reproductive and Therapeutic Cloning, UNESCO Division of the Ethics of Science and Technology, Paris, April 2004, available at unesdoc.unesco.org/images/0013/001342/134277e.pdf (last visited on 07 February 2006).

24 The official commentary to the Convention on Human Rights and Biomedicine does not exist and the traveaux preparatoire does not help in shedding a light on this issue. Furthermore, albeit Article 29 of the Convention on Human Rights and Biomedicine allows a possibility of requesting the European Court of Human Rights' advisory opinion on legal questions concerning the interpretation of the Convention, the ECHR allows individual States a wide discretion (known as the "margin of appreciation") in controversial policy areas. It has been submitted that because the concept of "embryo" is an extremely divisive issue, the ECHR would probably sustain from providing an explicit definition. See *Pattison, Shaun D./ Caulfield, Timothy*, Variations and Voids: the Regulation of Human Cloning Around the World, BMC Medical Ethics, Vol. 9, No. 5, available at http:// www.biomedcentral.com/1472-6939/5/9 (last visited on 12 February 2006).

encompasses only embryos created through fertilisation, or it also includes embryos created by means of procedures such as embryo splitting or somatic cell nuclear transfer. The answer to this question is of extreme importance for determining the legal status of therapeutic cloning,[25] because the creation of an embryo through somatic cell nuclear transfer is the starting point of the technique in question and the current state of the art is such that it cannot be applied on humans without previous research, not even in an experimental stage. Consequently, if the term "embryo" is to be defined in Croatian Law as including also embryos created through somatic cell nuclear transfer, than the prohibition of creation of embryos for research purposes is going to entail the prohibition of therapeutic cloning as well, and vice versa.[26] Another way of clarifying the current situation would be to explicitly allow or disallow therapeutic cloning as a whole, or somatic cell nuclear transfer only. This in turn would remove the need for construing the term "embryo", contained in the prohibition laid down by Article 18, paragraph 2 of the Convention on Human Rights and Biomedicine, for these purposes.

Even though the Croatian lawmaker has not yet taken a stand regarding therapeutic cloning, it has been said that the issue will be regulated by the new Medically Assisted Fertilisation Act, which should now be under preparation.[27] Regardless of which of the described solutions is eventually going to be chosen, the drafters of the future act need to be careful in designing the provisions on therapeutic cloning. In our view the provisions at issue should use somewhat flexible language so they could keep up with the fast developments in the field of biotechnology. Otherwise, the legislative efforts will surely prove short lasting and, as far as this highly controversial area of research is concerned, the current situation in which anything goes shall repeat itself in the future.

Human stem cell research

Similarly to the case of therapeutic cloning, Croatian legislation and by-laws concerning the use of human stem cells and their research are still scarce. The situation, however, varies depending on the type of stem cells concerned. For that reason, legal limitations pertaining to each type of stem cells, namely adult, foetal and embryonic stem cells shall be dealt with separately.[28]

Adult and umbilical cord stem cells

The use of adult stem cells and umbilical cord stem cells, particularly blood-forming stem cells, has been regulated in Croatia by the Taking and Transplantation of Human Body Parts for Medical Treatment Purposes Act (hereinafter: the Transplantation Act).[29] The introductory provisions of the Transplantation Act clarify that the provisions of the Act relating to tissues equally apply to cells, blood-forming stem cells being specifically mentioned.[30] However, its application to reproductive organs and tissues, embryonic or foetal organs and tissues, and blood, as well as blood prepara-

25 Interestingly, the Greece National Bioethics Commission considers therapeutic cloning to be exempted from the general prohibition of Article 18, paragraph 2 of the Convention on the Human Rights and Bio-medicine, due to a statement contained in the Preamble to the Protocol on the Prohibition of Cloning Human Beings that some cloning techniques themselves may contribute to scientific knowledge and its medical application. See Greece National Bioethics Commission: Stem Cells Recommendation, Athens, Greece, 21 December 2001, available at http://www.bioethics.gr/document.php?category_id=55&document_id=102 (last visited on 12 February 2006).

26 Should the latter solution prevail, regulations concerning research on human tissue will have to be applied in order to protect the rights of the donors of both the egg cell and the somatic cell involved. In Finland, for example, the creation of embryos for research purposes is prohibited by the Medical Research Act. However, since the same Act defines the embryo as "a living group of cells resulting from fertilization not implanted in a woman's body", therapeutic cloning is considered legal. Importantly, the Medical Research Act of Finland is based on the provisions of the Convention on Human Rights and Biomedicine. For the situation regarding therapeutic cloning in Finland see Finnish National Ethics Committees: Human stem cells, cloning and research, 2005, Helsinki, Finland, available at http://pro.tsv.fi/tenk/KantasoluENG.pdf (last visited on 12 February 2006).

27 Mr. Neven Ljubicic, the Head of the Ministry of Health and Social Welfare stated on 22 February 2005 that the New Medically Assisted Fertilization Act could be adopted by the end of 2005, after the Croatian Government defines its position regarding therapeutic cloning. However, this has not happened to date. The statement of Mr. Neven Ljubicic is available in written and in audio format at http://www.hrt.hr/auto/arhivvijesti/2005/02/22/HRT0043.html (last visited on 04 February 2006).

28 For a thorough analysis of the scientific, regulatory, ethical and socio-economic aspects of the research concerning human (embryonic) stem cells reference is made to the Commission Staff Working Paper Report on Human Embryonic Stem Cell Research, Brussels, 3.4.2003, SEC(2003) 441, accessible at http://ec.europa.eu/research/press/2003/pdf/sec2003-441report_en.pdf (last visited on 30 May 2006).

29 OG RC No. 177/2004.

30 See Article 1, paragraph 2 of the Transplantation Act.

tions, is explicitly excluded,[31] meaning that the Transplantation Act does not regulate the issues concerning embryonic or foetal stem cells.

Although the Transplantation Act was adopted with a primary purpose of determining the conditions under which taking and transplanting human body parts (organs and tissues) from living or deceased persons may be performed for transplantations as part of medical treatment,[32] Article 26 thereof provides that a human body part, obtained in the course of an intervention, can be stored and used for purposes different than those for which it was acquired, provided certain conditions are met.[33] Thus, the Transplantation Act allows the possibility for the adult stem cells, which have initially been taken for transplantation or during other interventions, to be used in genetic research. The conditions under which this is permitted are laid down in Articles 15 to 17, 22 and 25 of the Transplantation Act. These conditions differ depending on whether the donor is a living person or deceased, adult or minor.

When the donor of stem cells is a living person, the twofold condition has to be met. The first relates to mental and chronological age of the donor: it must be older than 18 years of age and must be capable of independent judgment.[34] This condition, however, does not apply in the case of umbilical cord blood-forming stem cells, which can be taken from the detached part of the umbilical cord of a live-born child.[35] The second condition relates to the issue of informed consent, prescribed also by Articles 5 to 9 of the Convention on Human Rights and Biomedicine. Namely, for stem cells to be isolated and used for genetic research, the donor must give a written consent in which it specifically allows the procedure of the isolation of stem cells.[36] This consent must be an expression of the donor's free will and must be given after the donor has been duly informed of the nature, purpose and course of the procedure, the likelihood of its success and usual risks involved. The donor must be informed of its rights under the Transplantation Act, in particular of the right to unbiased counsel regarding the health risks involved, by a medical doctor not taking part in the procedure at hand. Importantly, the donor can withdraw its consent at any time.[37]

If stem cells are taken from a deceased person,[38] it is necessary that this person did not, in its lifetime, oppose human body parts donation in a written document.[39] Furthermore, if the deceased person, from whom stem cells are to be taken, was a minor, or a person not capable of independent judgment, a written consent must be given by both of its parents, if both are living, or the person's ex lege representative, or guardian.[40] There is also a special provision in Article 24 of the Transplantation Act which relates to taking parts of body of a deceased

31 See Article 1, paragraph 3 of the Transplantation Act. In the Explanation to the Draft of the Final Proposal of the Act on Acquiring and Transplantation of Human Body Parts for Medical Treatment Purposes, it has been stated that matters concerning reproductive organs and tissues, embryonic or fetal organs and tissues, and blood, as well as blood preparations, shall be a subject of regulation in separate Acts. See the Draft of the Final Proposal of the Act on Acquiring and Trans-plantation of Human Body Parts for Medical Treatment Purposes, P.Z.E. No. 111, Ministry of Health and Social Welfare of the Republic of Croatia, Zagreb, October 2004, p. 25, available at http://www.sabor.hr/ Download/2004/11/26/PZ_111.pdf (last visited on 05 February 2006).

32 See Article 1, paragraph 1 of the Transplantation Act.

33 Substantially, this Article corresponds to Article 22 of the Convention on Human Rights and Biomedicine.

34 See Article 15 of the Transplantation Act.

35 See Article 20, paragraph 1 of the Transplantation Act. Paragraph 2 of the cited Article prescribes that the procedure for taking, storing and the use of umbilical cord blood-forming stem cells shall be defined in a by-law issued by the Minister of Health and Social Welfare. However, the by-law has not been enacted until the date of submitting this Report. Therefore, at this point in time it is not clear whether and whose consent is going to be necessary for the isolation, storage and use of umbilical cord blood-forming stem cells.

36 See Article 16 of the Transplantation Act.

37 See Article 17 of the Transplantation Act.

38 For example, one of the procedures utilizing stem cells taken from deceased persons is the so called Edmonton Protocol, in which islet cells are isolated from the pancreas of people who have died and are transplanted into patients with type I diabetes. See *Nobel, Mark*, Stem Cells: Facts and Fictions, available at http://www.nyamr.org/files/stemcellguide. pdf (last visited on 16 February 2006). For the purposes of the Transplantation Act, it is considered that the person from which human body parts are taken for the purpose of transplantation is dead, if it has been determined that its brain ceased to show any activity, in accordance to medical criteria and in a prescribed manner. See Article 21, paragraph 2 of the Trans-plantation Act. The manner, procedure and medical criteria for determining death are prescribed by the Rules on the Manner, Procedure and Medical Criteria for Determining Death of Persons Whose Body Parts can be Taken for Transplantation, OG RC No. 3/2006.

39 See Article 22 of the Transplantation Act. Therefore, if the written opposition to human body parts donation was not submitted during the person's life-time it is automatically presumed that the person did not oppose human body parts donation. The procedure for giving the written opposition to human body parts donation is prescribed in Articles 22 to 23 of the Transplantation Act.

40 Article 25 of the Transplantation Act.

person, who is not national of the Republic of Croatia or does not have permanent residence there, for the purpose of transplantation. In these circumstances the written consent is needed by that person's spouse or partner in the extra-marital union, child that reached the age of maturity, parent, or sibling that reached the age of maturity.

The Transplantation Act also prescribes fines for persons that use adult stem cells for research purposes without complying with the aforementioned conditions, in the range of 70,000 to 100,000 Croatian kuna.[41] Such actions have been labelled by the Transplantation Act as misdemeanours only, so they do not entail criminal liability.

In conclusion, it is important to underline that the Transplantation Act provides for the possibility of genetic research to be carried out on adult stem cells under condition that they were isolated in the course of a medical intervention. The direct donation of adult stem cells for research purposes has not been regulated in the Republic of Croatia at the time this Report is submitted.

Foetal stem cells

At the present time, there are no legal rules concerning genetic research on foetuses and foetal stem cells in the Republic of Croatia. Disappointingly, the Health Measures Act,[42] which is the only piece of legislation regulating the field of human reproduction currently in force in Croatia, even though virtually unconditionally allowing the abortion of foetuses not older than ten weeks, does not contain any provisions on handling the tissues originating from the termination of pregnancies.[43] Furthermore, the Convention on Human Rights and Biomedicine neither explicitly mentions foetuses, nor defines human body parts, while it prescribes in Article 22 that "when in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures." In the authors' view, it is questionable whether foetuses should be considered "parts of a human body" for the purposes of the Convention, or entities on their own merit.[44] It is therefore unclear whether the consent of the woman, on which the abortion is performed, constitutes under the Convention a condition that needs to be fulfilled for the research to be carried out on aborted foetuses, including the harvesting of stem cells. However, there are many arguments in support of the position advocating the need for the woman's consent, one of which being that the woman is given the right to freely decide on the destiny of the foetus in the sense of its removal from her body. Why then would she not have the right to decide on the future use, of course if such use is permitted under the law, of the removed foetus? Nevertheless, the problem is further deepened by the fact that the provisions of the Transplantation Act are explicitly said not to apply to foetuses or foetal organs, even though the Transplantation Act contains a provision identical to that of Article 22 of the Convention.[45] The Explanation to the Transplantation Act[46] proclaims that a separate legislation will be drafted to regulate matters concerning embryonic or foetal organs and tissues, which would surely be helpful in enlightening this issue, however, so far the competent Ministry of Health and Social Welfare failed to act accordingly. Therefore, as things stand now, there are neither legal obstacles nor prescribed procedures for utilising discarded foetuses for research purposes, including the purpose of harvesting foetal stem cells.

Obviously, the situation where it is neither clear in whom the rights over aborted foetuses are vested nor what the limits of those rights are is entirely unacceptable. Admittedly, the decision not to include matters concerning foetal organs or tissues into the Transplantation Act was not unexpected, due to more delicate ethical issues involved when the use of foetuses is concerned, compared to those that arise regarding adult tissues not related to reproduction. Nevertheless, it is surprising that the Government left this hypersensitive matter unregulated for such a long time, given that lack of any rules could evidently lead to misuses.

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41 Approximately 9,300 to 13,300 Euros. See Article 36 of the Transplantation Act.

42 Cited in supra n. 14.

43 See Articles 15 to 28 of the Health Measures Act. The termination of pregnancy is not allowed only in the case where the procedure would be harmful to the health of the woman involved.

44 Usually, such ethically sensitive issues are left to the national laws to be interpreted. See, for example judgment in the case Vo v. France (Application No. 53924/00) rendered on 8 July 2004, where the ECHR evaded the controversial issue of whether a foetus is a person for the purposes of Article 2 of the European Convention on Human Rights, which protects the right to life.

45 See supra text accompanying n. 31.

46 The Draft of the Final Proposal of the Taking and Transplantation of Human Body Parts for Medical Treatment Purposes Act, available at http://www.vlada.hr/Download/2004/05/27/24-02.pdf (last visited on 16 February 2006).

Embryonic stem cells

Equally to the case of therapeutic cloning, the only provision to somewhat regulate the embryonic stem cell research currently in force in Croatia is, again, Article 18 of the Convention on Human Rights and Biomedicine. The prohibition to create embryos for research purposes, contained in paragraph 2 of the cited Article, affects embryonic stem cell research inasmuch as it restricts it to embryonic stem cell lines harvested from the so called "supernumerary" or, simply, "spare" embryos, i.e. embryos left over from in vitro fertilisation (IVF) procedures performed in the course of assisted reproduction treatment. Other than that, there is no established policy on embryo or embryonic stem cell research in the Republic of Croatia. While the already mentioned Health Measures Act envisages two types of artificial insemination procedures available to couples with reduced fertility (homologue insemination[47] and heterologue insemination[48]) thus allowing the creation of spare embryos, it does not contain any provisions regulating their destiny.

In order to, inter alia, fill this colossal legal void, which obviously could be used as a harbour for various abuses, at the beginning of 2004 the Croatian Government formed a Working Group for the drafting of the new Medically Assisted Fertilisation Act. The intention was to include in the new Act the provisions regulating embryo research. The Draft Proposal of the Medically Assisted Fertilisation Act (hereinafter: the Government Draft)[49] was presented to and evaluated by the Government on 30 September 2004. Regarding embryo and embryonic stem cell research, the Draft reiterates the mentioned prohibition on the creation of embryos for research purposes, but it also envisages further restrictions, one of which being the prohibition of an in vitro development of an embryo that is older than fourteen days.[50] Furthermore, pursuant to Article 32 of the Government Draft, the scientific research on the embryo would be allowed for the exclusive purpose of protection and improvement of human life, if two requirements are met: first, a written consent has to be obtained from the couple, from which the embryo to be used for research originated, and, second, the approval of the National Committee for the Medically Assisted Fertilisation has to be issued.[51]

However, following the evaluation of the Government Draft, the Government of the Republic of Croatia failed to forward it to the Parliament for further procedure, initially giving no explanation for doing so, other than that the Draft needed refinement. Finally, on 22 February 2005, Mr. Neven Ljubi_i_, the Head of the Croatian Ministry of Health and Social Welfare, the body whose competences include drafting the proposal of the Medically Assisted Fertilisation Act, ended the silence and made a statement in which it clarified that the main reason for the withdrawal of the Draft were dilemmas concerning therapeutic cloning, but not pressure posed on the Government by certain parts of the public, namely, the Catholic Church, to completely ban artificial fertilisation procedures and the donation of oocytes and sperm cells, as has been speculated in the media.[52] He further stated that the new Medically Assisted Fertilisation Act could be adopted by the end of 2005, after the Croatian Government defines its position regarding therapeutic cloning.[53] However, until the day this Report is submitted, the new proposal of the Medically Assisted Fertilisation Act has

47 Insemination with the semen of the husband, as defined by article 30 of the Health Measures Act.

48 Insemination with the semen of a man other than the husband, as defined by Article 30 of the Health Measures Act.

49 The Governmental Draft and its Explanation are available at official page of the Government of the Republic of Croatia http://www.vlada.hr/Download/ 2004/ 05/27/24-02.pdfhttp://www.vlada.hr/Download/ 2004/09/30/41-02.pdf (last visited on 4 February 2006).

50 Article 31, paragraph 1 of the Government Draft

51 The purpose, structure and duties of the National Committee for the Medically Assisted Fertilisation have been prescribed in Articles 41-43 of the Governmental Draft.

52 See, for example, *Domazet, Nina*, Sef povjerenstva za zakon o umjetnoj oplodnji predlaze najrestriktivniji europski zakon, Novi list, 18 February 2005, available at http://www.novilist.hr/Default.asp?WCI=Rubrike&WCU=2859286028632 85A2863285A28582858285D286328962897289E286328632859285B2858285F285E285A28632863286328582863Z (last visited on 04 February 2006): "Suddenly, and without any explanation the Government withdrew its Act from procedure under the excuse that it should be harmonized with the EU. After that the Church began its campaign for a complete ban of artificial insemination." See also *Bajrusi, Robert*, Terapeutsko kloniranje: Vlada se priklonila Crkvi protiv znanstvenika, Nacional, No. 464, available at http://www.nacional.hr/ (last visited on 14 February 2006). The Croatian Catholic Church is relatively active in presenting its views on the issues that are subject matter of this Report, as evident from the proportion of its contributions in the total writings on these issues. See examples cited in infra n. 83.

53 The statement of Mr. Neven Ljubicic is available in written and in audio format at http://www.hrt.hr/auto/ arhivvijesti/2005/02/22/HRT0043.html (last visited on 5 February 2006).

not been presented by the Government, let alone adopted into a law,[54] thus leaving another significant area of genetic research insufficiently regulated.

Eugenic practices

In the past quarter of a century, eugenics became a hot topic as knowledge about genetics advanced considerably in the past half of the century, following the description of the DNA double helix by Watson, Crick and Wilkins for which they shared the Nobel Prize in Physiology or Medicine in 1962. Owing to the Human Genome Project, set up in 1988 by the United States National institutes of Health,[55] and similar activities, the successful alteration of the human species came within the reach of contemporary science, but did not entirely wash away the stigmatized connotations eugenics earned primarily due to misuses in the Nazis' era. Coupled with the apparent advantages of this development are also the fears that caution of possible unwarranted consequences the practices of "improving human genetic qualities" may have over the human evolution. Therefrom the need has arisen for their proper regulation.

In the Republic of Croatia, eugenic practices[56] are regulated by the Patient's Rights Protection Act.[57] This Act is another in the series of amendments resulting from the Croatian obligation to harmonise its legislation with the Convention of Human Rights and Biomedicine, and as such it should be construed in accordance with the Convention. Regarding eugenic practices, the Patient's Rights Protection Act contains a provision identical to that of Article 13 of the Convention on Human Rights and Biomedicine. Namely, Article 22, paragraph 1 of the Patient's Rights Protection Act prescribes that 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. Therefore, this provision allows somatic gene therapy that aims to correct the genetic defects in the somatic cells and to produce an effect restricted to the person treated, while it specifically precludes gene therapy on germ cells. However, closer examination of the Article reveals that procedures carried out as part of somatic gene therapy that can result in unwanted side effects on the germ cell line are not precluded.[58]

The Patient's Rights Protection Act also prescribes sanctions for the health institutions and companies acting in violation of the prohibition laid down in Article 22, paragraph 1, as well as for the responsible persons acting within those institutions or companies. The violation of this prohibition has been labelled a misdemeanour only, with the possible fines ranging from 10,000 to 50,000 Croatian kuna.[59]

Creation of chimeras and hybrids

With the rapid technological advancement, the scientists have increasingly attempted to produce chimeras and intergeneric hybrids involving human beings. Although it may be argued that humanlike animals may better serve the testing purposes for the new drugs than natural animals, may facilitate research that would improve understanding of the human species, or promise great prospects for growing organs for the purpose of transplantations, the creation of such creatures still poses enormous ethical concerns, above all since the unlimited practices of the sort carry an inherent risk of misuse.

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54 On 25 February 2005, the Member of Parliament *Frano Piplovic*, also a member of the Democratic Centre party, submitted its own proposal of the Medically Assisted Insemination Act (hereinafter: the DC Draft) to the Parliamentary Committee for Work, Social Politics and Health (hereinafter: the Parliamentary Committee). The DC Draft contained many solutions identical to those of the Governmental Draft, but it differed regarding the regulation of therapeutic cloning. Namely, Article 27, paragraph 3 explicitly prohibited "cloning of human beings for therapeutic purposes". Furthermore, Article 32, paragraph 2 prohibited "the creation of embryos for research purposes and their use for therapeutic and medical cloning". However, the DC Draft failed to define neither of the terms mentioned. The Parliamentary Committee considered the DC Draft on 25 May 2005 and made a decision not to support the proposal. For the text of the DC Draft see, P.Z. No. 263, Hrvatski Sabor, Zagreb, 25. February 2005. For the reasons for rejection of the DC Draft see, Report of the Parliamentary Committee for Work, Social Politics and Health on the Proposal of the Medically Assisted Insemination Act, Applicant *Frano Piplovic*, first reading, P.Z. No. 263, available at http://www.sabor.hr/default.asp?gl=200505240000001 (last visited on 20 February 2006).

55 See, http://www.genome.gov/ (last visited on 19 June 2006).

56 The term "eugenics", as used in this Report, means the modification in the human genome with the intention of modifying the genome of the descendants.

57 OG RC, No. 169/2004.

58 See Explanatory Report to the Convention on Human Rights and Biomedicine, points 73 and 92, available at http://www.ierm.at/Dokumente/Oviedo-rap-E.pdf (last visited on 10 February 2006).

59 1,300 to 6,500 Euros, approximately.

Currently, not a single piece of legislation that would regulate this obscure field of genetic research is in force in Croatia.[60] Nonetheless, the awareness of the need to change this situation evidenced in the Government Draft is encouraging. Even though the Draft was supposed to primarily regulate human infertility interventions, it also concerned some aspects of transgenics by prescribing a prohibition of several procedures directed at the creation of chimeras and hybrids. Namely, Article 31, paragraph 1 of the Government Draft explicitly banned the following procedures:

- the insemination of a human oocyte with animal semen,
- the insemination of an animal oocyte with human semen,
- embryo manipulation by transplantation of parts of other human or animal embryos,
- the implantation of human oocytes or embryos into an animal, and
- the implantation of human oocytes or embryos into a woman.

The Government Draft did not stop at the mere proclamation of the unacceptability of these procedures, but it prescribed penal provisions criminalizing such interventions and laying down sanctions for the perpetrators, equal to those for reproductive cloning, i.e. imprisonment for at least six months and not more than five years.[61]

Unfortunately, the Government Draft never reached the Parliament, let alone got its approval, and its destiny still remains unknown,[62] thus leaving a door wide open for murky experiments that are entirely objectionable from the ethical point of view for many reasons, one of which is that they could lead to unnecessary suffering of the creatures potentially created. This is a far too sensitive area of research to be regulated only by ethical codes, which in reality are hardly persuasive.[63] Those codes provide nothing more than guidelines for the conduct of scientists and are effective inasmuch as the person's scruples are not distorted. The sooner the Croatian Government realizes the insufficiency of the existing legislation and the dangers that this situation brings to society, the better. Otherwise, Croatia might attract foreign investments of the sort it actually never intended to.

Ethical Conduct of Scientists Involved in Genetic Research

In addition to state drafted and enacted laws, genetic research is in many ways regulated also by ethical codes adopted within the framework of professional associations or research institutions such as universities. The most important and perhaps the most widely applicable code of the sort in the Republic of Croatia is the Code of Medical Ethics and Deontol-ogy (hereinafter: the Ethical Code).[64] Besides many provisions regulating the expected conduct of medical doctors in various situations, the Code contains two Articles that are directly relevant to genetic research.

Article 6 of the Ethical Code lays down the general policy to be followed when performing biomedical research, the basic rule being that, in research, medical doctors should strictly adhere to the provisions laid down by the World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects and its revisions.[65] Importantly, the welfare of an individual is said to have primacy over the interests of science and the society. Accordingly, medical doctors involved in research have a duty to protect life, health, privacy and dignity of the human research

60 Transgenics research is also not regulated in some other countries, such as the United States of America, either. However, many countries have enacted laws that specifically regulate chimera and hybrid research, although various national laws are very heterogeneous. For the analysis of the situation in Canada, see *Robert, Jason Scott*, Regulating the creation of novel beings, Health Law Review, Volume 11, Number 1, pp. 14-20, available at http://www.law.ualberta.ca/centres/hli/pdfs/hlr/v11_1/robertsfrm.pdf (last visited on 13 February 2006). Transgenic practices are explicitly prohibited in Germany by the provision of Article 7 of the Embryo Protection Act, Gesetz zum Schutz von Embryonen (Embryonenschutzgesetz – ESchG), BGBl. I 69, 19 December 1990, p. 2746.

61 See Article 48 of the Government Draft.

62 See supra section II.2.3.

63 See infra section III.

64 OG RC No. 47/2004. The Ethical Code has been adopted by the Croatian Chamber of Medical Doctors and is applicable to every person license to practice medicine in the Republic of Croatia. See the preamble of the Ethical Code. For more information on the Croatian Chamber of Medical Doctors, see http://www.hlk.hr (last visited on 20 February 2006).

65 The Declaration of Helsinki (Document 17.C) is an official policy document of the World Medical Association, the global representative body for physicians. It was first adopted in 1964 (Helsinki, Finland) and revised in 1975 (Tokyo, Japan), 1983 (Venice, Italy), 1989 (Hong Kong), 1996 (Somerset-West, South Africa) and 2000 (Edinburgh, Scotland). Note of clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002. The World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects is available at http://www.wma.net/e/policy/b3.htm (last visited on 21 February 2005).

subjects.[66] A large portion of the Article is devoted to the issue of informed consent, which is regulated in quite detail.[67] The Article also prescribes requirements that have to be met for specific research to be conducted, the most important of them being that the research plan has to be approved by an independent committee, especially regarding the scientific and ethical acceptability of research.[68]

The second provision relating to the field of genetic research is Article 7 titled "The Human Genome". This Article largely relies on the provisions of the Convention on Human Rights and Biomedicine and of the Protocol on the Prohibition of Cloning Human Beings. In fact, it contains provisions identical to Article 11 of the Convention concerning non-discrimination,[69] Article 12 concerning predictive genetic tests,[70] Article 13 concerning interventions on the human genome,[71] and Article 1 of the Protocol concerning the prohibition of cloning human beings.[72]

The Ethical Code also proclaims that adherence to the rules set therein is an obligation of every medical doctor, with sanctions of disciplinary nature to follow for persons defying its rules.

Transparency and Public Accessibility to Genetic Research

As in many countries before, the accelerated development of biotechnology and the importance of inducing an informed public debate regarding the issues involved lead to the establishment of the first Croatian national ethics council under the name the "Committee for Issues Related to Cloning and Human Genome" (hereinafter: the First Bioethics Committee). The First Bioethics Committee was established on 30 April 1998 as a Government agency, with the goal to systematically follow the problems and assist in resolving issues stemming from research related to the human genome and cloning, as well as to advise the Government in that respect.[73] The Committee consisted of many renowned scientists, but also legal and theological scholars and experts,[74] and, given its wide field of activities,[75] it was supposed to have a huge impact on the Croatian legislature regarding the enactment of new laws that would regulate genetic research. However, in the three years in which the Committee was in function not a single legal instrument was adopted to regulate the field, with the exception of signing of the Convention on Human Rights and Biomedicine by the Republic of Croatia, which took place on 7 May 1999.

On 12 April 2001 the First Committee was dissolved and replaced by the "National Bioethics Committee for Medicine" (hereinafter: the Second Bioethics Committee),[76] which was founded to evaluate ethical and legal matters in a somewhat wider field than that of cloning and the human genome. The main task of the Second Bioethics Committee has been thus set to involve giving recommendations, opinions, reports and guidelines for adoption of laws in the following fields: biomedical research on human beings, medical ethics and deontology, family planning and termination of pregnancies, medically assisted fertilisation, gene techniques, human genome, protection of the human embryo, cloning, transplantation of human tissues and organs, xenotransplantation, compulsory medical treatments, treatments of patients with terminal conditions, euthanasia and specialisation in the

66 Article 7, paragraph 2 of the Ethical Code.

67 See Article 7, paragraphs 6-8 of the Ethical Code.

68 The national committee that evaluates research projects in the Republic of Croatia regarding their ethical acceptability is the National Bioethics Committee for Medicine. See infra section IV.

69 Article 7, paragraph 1 of the Ethical Code states: "Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited."

70 Article 7, paragraph 2 of the Ethical Code states: "Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling."

71 Article 7, paragraph 3 of the Ethical Code states: "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."

72 Article 7, paragraph 4 of the Ethical Code states: "Creation of genetically identical human beings is considered as being contrary to ethics and the respect for human dignity. Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited."

73 Article II of the Decision to Establish the Committee for Issues Related to Cloning and Human Genome, OG RC No. 66/1998.

74 For the membership of the First Bioethics Committee, see Article III of the Decision to Establish the Committee for Issues Related to Cloning and Human Genome, OG RC No. 66/1998.

75 See Article II of the Decision to Establish the Committee for Issues Related to Cloning and Human Genome, OG RC No. 66/1998.

76 See Article VIII of the Decision to Establish the National Bioethics Committee for Medicine, OG RC No. 35/2001.

field of bioethics.[77] Several laws that contain provisions related to these fields were indeed adopted in the last couple of years, the most important of them being the already mentioned Transplantation Act,[78] the Patient's Rights Protection Act[79] and the Penal Amendment Act 2004.[80] However, the provisions of the cited acts, which relate to the aforementioned fields in which this Committee is acting, are practically translations of the provisions of the Convention on Human Rights and Biomedicine, and do not attempt to settle some uncertainties brought by the Convention. The Government Draft on the Medically Assisted Fertilisation Act[81] was drafted with that intention, and it gained full support of the Second Bioethics Committee, but was afterwards withdrawn by the Government. This was followed by the appointment of twenty new members to the Second Bioethics Committee.[82] It would be recommendable if the newly constituted Committee would adopt a more transparent policy and make its recommendations, opinions, reports or guidelines easily available to the public, such as by setting an internet web site and placing there the relevant information. This is truly important since the work of the Committee is concerned with the areas that the public is very interested in and needs to be properly informed of in every pluralist society.[83]

Intellectual Property Protection of genetic Research Results

In the Republic of Croatia genetic research results can be protected through the patent system, which is regulated by the Patent Act of 2003.[84] The provisions of the Patent Act are harmonised with the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (hereinafter: the Biotech Directive),[85] as well as with the provisions of the European Patent Convention (hereinafter: the EPC).[86]

77 Article III of the Decision to Establish the National Bioethics Committee for Medicine, OG RC No. 35/2001.

78 Cited in supra n. 29.

79 Cited in supra n. 57.

80 Cited in supra n. 6.

81 Cited in supra n. 49.

82 See Decision on Dismissal of the Members of the National Bioethics Committee for Medicine, OG RC No. 159/2004. See also Decision on Appointment of the Members of the National Bioethics Committee for Medicine, OG RC No. 159/2004.

83 The need to increase intensity and particularities of the biotechnology was also identified to exist in the European Union Member States. See *Midden, Cees/ Boy, Daniel/Einsiedler, Edna/Fjaestad, Björn/Liakopoulous, Miltos/ Miller*, *Jon D./Ohman, Susanna/Wagner, Wolfgang*, The Structure of Public Perceptions, in: Bauer, Martin W/Gaskell, George (eds.), Biotechnology – The Making of a Global Controversy, Cambridge University Press/ Science Museum, Cambridge/London, 2002, pp. 203-223. In Croatia the situation is even more arduous because not only that the competent public debate is virtually non-existent in Croatia, but is also quite scarce in the scientific circles. Moreover, the preponderant part of publications is concerned with theological arguments. See, for example, Akademja Medicinskih Znanosti Hrvatske, Horizontalno sirenje gena i ljudsko zdravlje, Zagreb, 2000; Eticki aspekti terapijskog kloniranja i transplantacije organa, Zagreb, 2003; *Grbac, Josip*, Moralne dileme genetskog istrazivanja, Istarzka Danica, 2000, pp. str. 52-57; *Hlaca, Nenad*, O bioetici u povodu potpisa u Vijecu Europe dvaju medunarodnih dokumenata s bioeticnim sadrzcajima, Vladavina prava, Vol. 2, Nos. 3/4, 1998, pp. 45-53; ID., Prilog raspravi o zabrani kloniranja ljudskih bica, Zbornik Pravnog fakulteta Sveucilista u Rijeci, Vol. 20, No. 1, 1999, pp. 437-447; *Matuliz, Tonci*, Bioeticka dilema: kloniranje ljudskih bica? (I. dio): povijesno-biomedicinska i psiho-socioloska analiza nastanka jednog "klona", Vladavina prava, Vol. 3, No. 5, 1999, pp. 19-40; ID., Bioeticka dilema: kloniranje ljudskih bica? (II. dio): biomedicinske i zakonske reperkusije, Vladavina prava, Vol. 3, No. 6, 1999, pp. 31-52; ID., Bioeticka dilema: kloniranje ljudskih bica? (III. dio): filozofsko-antropoloske i eticke reperkusije, Vladavina prava, Vol. 4, No. 1, 2000, pp. 25-50; ID., Bioetika i genetika: medicinska praksa izmedu eugenike i jatrogene bolesti, Bogoslovska smotra, Vol. 75, No. 1, 2005, pp. 185-210; *Pozaic, Valentin*, Kloniranje kao pitanje odgovornosti, Socijalna ekologija, Vol. 6, No. 3, 1997, pp. 297-307; ID., Manipulacije ljudskim embrijem uime ljudskih prava, Vjesnik Zadarske nadbiskupije, Nos. 1-2, 2002, pp. 29-41; *Pozaic, Valentin/ Svajger, Anton*, U povodu vijesti: kloniran je ljudski embrio, in: *Svajger, Anton* (ed.), Spisi medicinske etike, Zagreb 2004, pp. 147-156; *Viskovic, Nikola*, Bioetika i biomedicinsko pravo, Zbornik radova Pravnog fakulteta u Splitu, Vol. 32, Nos. 1/2, 1995, pp. 67-83; *Volaric-Mrsic*, Ana (ed.), Status ljudskog embrija, Zagreb, 2001.

84 OG RC No. 173/03 and 87/2005. The 110th anniversary of patent law was recently been marked in the Republic of Croatia (the Common Hungar-Croatian Parliament ratified the Copyright Act on 4 May 1884, and the Patent Act on 7 July 1895).

85 The text of the Biotech Directive is available at http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf (last visited on 22 March 2006).

86 Croatia is not yet a member state of the European Patent Convention. However, on June 2003, the President of the European Patent Office and the Minister for European Integrations of the Republic of Croatia signed an agreement on co-operation in the field of patents (Co-operation and Extension Agreement). The agreement entered into force on 1 April 2004. Thereof, it is possible to extend the protection conferred by European patent applications and patents to the Republic of Croatia. Essentially, the extended European patent applications and patents

Substantive requirements for patentability of genetic Research Results

According to Article 5 of the Patent Act, a patent can be awarded to any invention from any technological field that satisfies the three traditional requirements for patentability: novelty, inventive step and industrial applicability. Under these conditions a patent can be awarded also for an invention that concerns a product consisting of or containing biological material, a process by means of which biological material is produced, processed or used, and biological material which is isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature. Similarly to the Biotech Directive, the Patent Act defines biological material as any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.[87]

Exclusions to patentability applicable to genetic research results

The Patent Act envisages the same exclusions to patentability that can be applicable to patentability of genetic research results, as do the Biotech Directive and the EPC. Thus, the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.[88] However, an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.[89]
Importantly, Article 7, paragraph 1 of the Patent Act also envisages the ordre public and morality exclusion to patentability that has a significant impact on the patentability of genetic research results:

Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public and morality.

As can be seen, the exclusion as prescribed in the Patent Act does not contain the so called qualification clause, contained in both Article 6(1) of the Biotech Convention and Article 53(a) of the EPC, under which the exploitation shall not be deemed so contrary simply because it is prohibited by legislative or other legal instrument. In addition to the general ordre public and morality clause, Article 7, paragraph 2 of the Patent Act specifies what sorts of inventions shall be considered to fall under the exclusion, thereby providing a non-exhaustive list of unpatentable inventions:

- processes for cloning human beings,
- processes for modifying the germ line genetic identity of human beings,
- uses of human embryos for industrial or commercial purposes,
- processes for modifying the genetic identity of animals which are likely to cause then suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Although not explicitly prescribed as being contrary to ordre public and morality, it seems that inventions involving genetic research results, such as those related to embryonic and foetal stem cells, therapeutic cloning or the creation of chimeras and hybrids would be caught by the exclusion.[90] However, this should be understood as a tentative conclusion by the authors of this Report, since, to their knowledge, there have been no attempts before the State Intellectual Property Office of the Republic of Croatia to obtain a patent for any of the inventions related to these areas hitherto. For the same reason the issue of patentability is not discussed in more detail in this Report.

Conclusion

Genetic research involving humans as well as the commercialisation of its results both raise intricate ethical questions. On the one hand, this research is

enjoy the same protection in the Republic of Croatia as patents granted by the EPO for member states. Articles 99-109 of the Croatian Patent Act as in force from 1 January 2004 govern the extension of European patents in the Republic of Croatia. See http:// www.european-patent-office.org/epo/pubs/oj004/03_04/03_1174.pdf (last visited on 22 March 2006).

87 Article 5, paragraph 2 of the Patent Act and Article 2, paragraph 1(a) of the Biotech Directive.

88 Article 6, paragraph 2 of the Patent Act and Article 5, paragraph 1 of the Biotech Directive.

89 Article 6, paragraph 2 of the Patent Act and Article 5, paragraph 2 of the Biotech Directive.

90 For the publication of a Croatian scholarly position on patentability of the inventions related to human embryonic stem cells which are equally applicable to the Croatian Law on the point see, *Saunders, Eliza/ Mutabzija, Jasmina*, Patentability, Ordre Public and Morality: The Case of Inventions Involving Human Embryonic Stem Cells – an EU, US and Australian Perspective, Intellectual Property Forum, Issue 59, 2004, pp. 14-34, especially 18-23.

seen as the catalyst to facilitate scientific advancement possibly having enormous potential in treating hitherto incurable diseases, such as Parkinson's disease, diabetes or heart failure. On the other hand, moral dilemmas are posed as to justifiableness of research, such as that concerning human embryonic stem cells or manipulating with human biological material, all the more since the aforementioned potentials are rather uncertain at this point in time given the scarcity of expert's knowledge and technology in the field. This Report does not intend to discuss the issues of conflict between different values, opposite rights and obligations, or contrasting interests, because they are the prerogatives of every individual and every society, including each Croatian citizen and the Croatian society as a whole. However, a pluralist society has to increase public awareness of these issues, so that the citizens may engage in an informed debate and make a knowledgeable decision.

While some of the practices dealt with in this Report have been commercialised, other still have not and are regulated insofar as the research is concerned. Furthermore, will inventions based on the latter become patentable in the future is the issue of balance the state has to maintain between costs and benefits thereof, in a view of investor's interests, society's commercial and social welfare, freedom of research, as well as ethically sensible aspects related to human rights, human dignity and religious and other convictions. In doing so, history of science and its mis(uses) in practice certainly may teach a good lesson and send the message of the need to increase awareness of the potential hazards an overcredulous acceptance of the "promising" new practices may have over human kind.