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SPECIFIC HUMAN RIGHTS ISSUES

Human rights and bioethics

Expanded working paper submitted by Ms. Iulia-Antoanella Motoc* in accordance with Sub-Commission decision 2002/114

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* This report was submitted late so as to include the most updated information possible.

Introduction

1. In its decision 2002/114, the Sub-Commission on the Promotion and Protection of Human Rights decided to entrust Ms. Motoc with the task of preparing an expanded working paper on the question of bioethics and human rights, to be considered at its fifty-fifth session. Ms. Motoc had submitted to the Sub-Commission a working paper (E/CN.4/Sub.2/2002/37) in accordance with decision 2001/113, identifying the diverse issues and problems involved in the discussion of this question and containing a number of proposals for a study on the follow-up to the Universal Declaration on the Human Genome and Human Rights.

2. In resolution 2003/69 the Commission on Human Rights, affirming that 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, and recalling that article 10 of the Universal Declaration on the Human Genome and Human Rights affirms that no research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals, again requested the Sub-Commission to consider what contribution it can make to the reflections of the International Bioethics Committee on the follow-up to the Universal Declaration and to report on this matter to the Commission at its sixty-first session.

3. The reader is referred to the first working paper for a presentation of the Human Genome Project and the questions it has raised in the fields of science, law and ethics. The fundamental questions raised by the research on the human genome were expressed by the German philosopher Jurgen Habermas:

> "What is so unsettling is the fact that the dividing line between the nature we are and the organic equipment we give ourselves is being blurred …The well-known arguments taken from the abortion debate are, I believe, setting the wrong course. Gene manipulation is bound up with issues touching upon the identity of species, while such an anthropological self-understanding provides the context in which our conceptions of law and morality are embedded. My particular concern is with the question of how the biotechnological de-differentiation of the habitual distinction between the 'grown' and the 'made', the 'subjective' and the 'objective', may change our ethical self-understanding as members of the species and how it might affect the self-understanding of a genetically programmed person. We cannot rule out that knowledge of one's own heredity factors being programmed may put certain constraints on an individual's right to an open future, while undermining the essentially symmetrical relations between free and equal human beings."[1]

4. Efforts to ascertain the structural design of our genetic heritage pledge a major transformation in health care. Notwithstanding the foreseen returns, these advances engender global concerns about the implications of such developments, in particular on human rights, public health and trade.[2] Genetics has been used to justify policies ranging from compulsory sterilization to eugenic practices and genocide. Alarm also arises concerning whether our genetic structure should be translated into a subject of propriety rights, allowing a few companies to have power over access to gene-based products fundamental to the health of all of humanity. It is largely admitted that while the science of mapping and sequencing the human genome is in progress, the legal framework lags far behind.[3]

5. Attempts have been made by several international organizations to address genomic research. Taken together, the norms relating to the human genome form an incoherent picture. Recent advances in genetics seem to have given rise to another conflict between the health law regime, the intellectual property regime and the human rights regime. The priority given to the human rights regime can be legally justified by reference to Article 103 of the Charter of the United Nations, which stipulates that "in the event of a conflict between the obligations of the Members of the United Nations under the present Charter and their obligations under any international agreement, their obligations under the present Charter shall prevail." This clause was invoked in order to suggest that the maintenance of peace and security and the protection of human rights have priority over all other international regimes, given the fact that the Charter indicated that they are the main purposes of the United Nations.[4]

6. The purpose of this working paper is to outline the main questions to be analysed in a study of the subject and thus provide a basis for discussion by the Sub-Commission. Consequently, it is to be understood as a continuation of the first working paper (E/CN.4/Sub.2/2002/37) and as a set of hypotheses requiring further elaboration. It tries to address some of the conflicts from a human rights perspective, taking into account four issues discussed in the previous paper: (a) the human genome as the common heritage of mankind; (b) manipulation of the human genome and human rights; (c) discrimination and the human genome; (d) intellectual property and human rights.

I. THE HUMAN GENOME: COMMON HERITAGE OF HUMANITY

7. Article 1 of the Declaration on the Human Genome and Human Rights of the United Nations Educational, Scientific and Cultural Organization (UNESCO) stipulates: "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. In a symbolic sense, it is the heritage of humanity."

8. The "common heritage of mankind" (CHM) principle is the legal notion that all people have an equal proprietary interest in the natural world. The CHM doctrine, which is applied to the deep seabeds, Antarctica, the moon and other celestial bodies and certain worldwide historical sites, includes the following characteristics: (i) no country can appropriate for itself the territory in question; (ii) all States share responsibility for managing the territory; (iii) all States must share in the benefits from exploitation of the territory or its resources; and (iv) all countries must use the territory exclusively for peaceful purposes.[5] The United Nations tends to apply the CHM concept uniformly to environmentally vulnerable sites.

9. The human genome is considered to be the blueprint of humankind's common heritage; it is a more integral part of humanity than the items that the CHM principle traditionally covers. It was considered that applying this definition to the Human Genome Project (HGP)[6] would result in the following determinations: (i) the genome could not be appropriated by any country or private corporation within that country; (ii) all States would share responsibility for setting regulations and laws for permissible uses of the genome; (iii) all States would share in the benefits derived from HGP, which would mean that all gene sequences would be publicly accessible; (iv) the genome would be reserved exclusively for peaceful uses; and (v) the

international community would have shared responsibility for preserving the genome intact for future generations. A treaty granting the HGP CHM status would eliminate State concerns about protecting their investments.[7]

10. The CHM language has long been and still is subject to different interpretations by developed and developing countries. Developing countries assert that the CHM principle gives humanity collective ownership, requiring profits to be divided among all nations. They consider that the collective ownership theory requires the establishment of a unique international authority with the right to distribute resources among States, including States not participating in the harvesting activities.

11. The Third United Nations Convention on the Law of the Sea (UNCLOS III) Convention describes in great detail the international regime that was supposed to administer the exploitation of the deep seabed. It provides for the establishment of an International Seabed Authority to regulate mining activities in the deep seabed and "the Enterprise", an intergovernmental mining company to be run by the Seabed Authority. Private companies wishing to mine the deep seabed are required to apply for a licence from the Seabed Authority, identify two prospective mining sites of equal commercial value, and catalogue the equipment and methods to be used. The Seabed Authority selects one of the sites and reserves the other for the Enterprise to exploit, either by itself or in cooperation with developing countries. The developing countries designed the Enterprise so that the profits from deep seabed mining would be shared by all States regardless of whether they had been involved in the mining venture.

12. Most developed countries did not ratify the UNCLOS III Convention because of the Enterprise provisions.[8] UNCLOS III was revised 12 years after its adoption in order to draw in the developed countries and set up an effective regime. The changes included restructuring the deep seabed mining regime along the lines of free market principles and eliminating the mandatory transfer of technology and production ceilings provisions.

13. The 1979 Agreement governing the Activities of States on the Moon and Other Celestial Bodies ("the Moon Treaty") does not sketch out an international outer space administrative regime. Article 11 provides for the adoption of an international regime to govern the exploitation of natural resources of the moon and other celestial bodies when "such exploitation is about to become feasible". The General Assembly was to review the Moon Treaty 10 years after its entry into force to determine whether revision was necessary in view of the need to establish an international administrative regime. However, neither the General Assembly nor the States parties met to settle this question, which was interpreted as reluctance to see such a regime established.[9]

14. The evolution of the concept of CHM has shown that developed and developing countries have discordant interpretations and different views concerning an international regulatory regime. An international regime concerning the human genome must be interpreted so as to assure an equilibrium between the needs of both developed and developing countries.

II. HUMAN GENETIC MANIPULATION AND HUMAN RIGHTS

15. There are two types of cloning: therapeutic and reproductive. These are distinguished by the uses to be made of cloned embryos. Therapeutic cloning is tied to the production of stem cells, which are unspecialized cells at an early stage of development that can divide and differentiate into the numerous types that comprise the cells of the tissues and organs of the body. Stem cells have a central role in human growth and provide a continuous source of new cells for the regeneration of diseased tissue. Therapeutic cloning refers to the use of the product of cellular nuclear replacement for research and therapeutic purposes; embryos are not allowed to develop or be implanted in a woman's uterus. Reproductive cloning refers to the actual implantation of the blastocyst resulting from cellular nuclear replacement, which is the purpose of performing the procedure.[10]

16. The successful cloning of Dolly the sheep made the world community aware of the possibility of applying similar procedures in humans.[11] Potential applications for human cloning have been improved by advances in stem cell technology. The stated intention of those who announced that they had cloned the first human embryo is to make the most of this technology for the production of human stem cells.

17. Of more immediate significance is the cloning of human tissue for therapeutic purposes: the manipulation of the DNA of those tissues in order to alleviate the suffering caused by diseases such as Alzheimer's, diabetes, Parkinson's, cardiovascular disease and various genetically linked cancers. Therapeutic cloning of tissue would be used to attain such aims as the substitution of bone, tissue, skin, and cartilage and the renewal of spinal cord tissue; it is not meant to produce a whole human being.

18. The three principal instruments that address human genetic manipulation are the Universal Declaration on the Human Genome and Human Rights, the European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine) Convention and its Additional Protocol on the Prohibition of Cloning Human Beings. An international convention against reproductive cloning was proposed at the level of the United Nations. Because of the deep sense that humanity is related to but distinct from other beings, changing our nature necessarily threatens to destabilize human dignity[12] as a fundamental human right.[13]

19. Article 2 of the UNESCO Declaration states that "dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity" and considers reproductive human cloning as contrary to human dignity and shall not be permitted (art. 11).

20. The purpose of the European Convention on Human Rights and Biomedicine is to safeguard human dignity and the identity of all human beings and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine. The Additional Protocol states that the deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes a misuse of biology and medicine (preamble).

21. Article 3 of the Charter of Fundamental Rights of the European Union states: "Everyone has the right to respect for his or her physical and mental integrity" and "In the field of medicine

and biology the following must be respected in particular: the free and informed consent of the person concerned, … the prohibition of eugenic practices, in particular those aiming at the selection of persons … the prohibition of the reproductive cloning of human beings".

22. The Committee on Economic, Social and Cultural Rights took into account in its general comment no. 14, that "every human being is entitled to the enjoyment of the highest attainable standard of health conducive to a life in dignity". The Committee catalogued 14 rights related to the right to health. The general comment acknowledges that genetic factors play a role in determining an individual's health, but does not address genetic manipulation or cloning specifically. The State's obligation to respect the right to health includes ensuring that government agencies do not engage in hazardous genetic manipulation; the obligation to protect also includes preventing the biotechnology industries from engaging in such activities.

23. Article 23 of the International Covenant on Civil and Political Rights recognizes the right of men and women of marriageable age to marry and to found a family. Cloning is disparaging of the rights of children and their human dignity. It infringes the child's right to an open future and binds that child as a genetic prisoner of another person's genome.

24. George Annas has stated that human cloning threatens our human condition and therefore our humanity: "Can universal human rights and democracy, grounded in human dignity, survive human genetic engineering? Without clear goals, the market will define what it is that makes a better human. Mass marketing and advertising will encourage us to conform to some culturally-constructed ideal, rather than celebrate, or even accept, differences".[14]

25. Genetic manipulation could be considered as inhuman treatment because a person who would be a new species or a subspecies of human would essentially not be a holder of human rights. If human physical traits were modified to a great extent then the clone would certainly be "inhuman". Human-replication cloning and other such forms of genetic engineering have to be qualified as a category of crimes against humanity. It has been proposed that the International Criminal Court should investigate and punish human cloning.[15]

26. Along a similar line of thinking, the international community has noted that human dignity and human rights derive from our common humanity and that while genetic science has the power to open up vast prospects for improving health, it also has the power to diminish humanity fundamentally by producing a child through human cloning or by intentionally producing an inheritable genetic change.

27. Human cloning, should it allow science to produce children with predetermined genotypes, or by altering fundamental human characteristics, might cause these children to be deprived of their human rights or to be discriminated against. Considering that the creation of a new species or subspecies of humans could easily lead to genocide or slavery, it was proposed to adopt a convention on the preservation of the human species.[16]

28. Article 12 of the UNESCO Declaration stipulates that "benefits from advances in biology, genetics and medicine concerning the human genome shall be made available to all, with due regard for the dignity and human rights of each individual" and that applications in these fields shall "seek to offer relief from suffering and improve the health of individuals and humankind as a whole".

29. UNESCO recommends that its member States allow researchers to enjoy the degree of autonomy appropriate to their task and to the advancement of science and technology and to take fully into account that creative activities should be promoted in the national science policy on the basis of utmost respect for autonomy and freedom of research necessary to scientific progress.

30. The European Convention acknowledges freedom of scientific research and testing for health-related research. Both the European Convention and the UNESCO Declaration make an exception for freedom of research where human welfare or human rights would suffer.

31. A proposal for a convention banning reproductive cloning was discussed by the General Assembly at the end of 2002. Some States proposed the elaboration of a convention banning reproductive cloning, which would send a strong message that the reproductive cloning of humans was unethical and illegal. It was proposed to address reproductive cloning, and therapeutic cloning later. It was considered that this method accepted the intricate and conflicting views about therapeutic and experimental cloning, while at the same time reflecting the consensus that reproductive cloning was unacceptable. In view of the fact that work on human cloning was taking place, it was considered imperative to elaborate a convention against it as soon as possible.

32. Other States support the elaboration of a convention calling for a comprehensive ban on both reproductive human cloning and on human cloning for therapeutic and experimental purposes. Since the technology for both was the same, it was considered that a partial ban on reproductive cloning would be ineffective and would send the wrong message by implicitly authorizing the creation and destruction of human embryos for experimentation. Further, a partial ban on cloning would create legal uncertainty. The distinction between reproductive and other cloning masked the reality that a human being was being created for the purpose of destroying it to produce embryonic stem cell lines or to carry out other experiments - techniques that were highly controversial and raised profound ethical and moral questions.

33. It was pointed out that human embryonic cloning conflicted with international legal norms protecting human dignity. Other cloning techniques such as adult stem cell research did not pose a problem and would not be covered by a comprehensive ban. Alternative approaches included a moratorium pending the entry into force of a convention against reproductive human cloning; a permanent ban on reproductive cloning and a short-term ban on therapeutic cloning to buy time for study, and a two-tiered approach focusing on reproductive cloning and containing provisions on other cloning activities that the parties to the convention could opt in or out of. It was suggested that future work in the General Assembly could include consideration of whether to establish an international cloning commission and the promotion of international cooperation geared towards substitute technologies for developing countries.[17]

III. DISCRIMINATION AND THE HUMAN GENOME

34. The right to non-discrimination and to equal protection of the law in the field of bioethics is stipulated by the UNESCO and Council of Europe texts and the Charter of Fundamental Rights of the European Union. The UNESCO Declaration states: “No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity” (art. 6).

35. Discrimination issues come up first and foremost with respect to genetic testing or screening, the results of which could bring employers or insurers to exclude persons from employment whose tendency to disease or other health conditions is high, as exposed by their gene sequencing. Present-day debate of the social implications of HGP focus on discrimination against individuals in the employment and insurance contexts. Applicants who reveal predispositions to genetic disorders may be denied employment, refused promotions, or restricted from access to positions entailing risk. Use of genetic information in this way could supposedly promote good organization and lower costs by creating a more prolific workforce. Those who oppose genetic testing in the employment context claim that the tests will be randomly applied, have limited prognostic truthfulness, will be unable to determine the extent to which an employee may be affected by genetically inclined circumstances, and may call attention to disorders that do not actually interfere with job functioning.[18]

36. The right to privacy and the related right to seek, receive and impart information have both been incorporated in what is sometimes called “the emerging international law for human genetic manipulation”. The UNESCO Declaration stipulates “genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law (art. 7)”. Article 10 of the European Convention provides that everyone has the right to respect for private life in relation to information collected about his or her health.

37. The protection of privacy includes health-related information. Human genetic data collection only increases the need for protection. People whose DNA is analysed also have a right to know who is collecting the information, why, where it is stored, and who has access to it.[19]

38. Experimental and therapeutic interventions for the purpose of genetic engineering raise special problems regarding free consent to medical or scientific experimentation. The UNESCO Declaration and the European Convention require a risk-benefit assessment with prior, free and informed consent. Nevertheless, most decisions will require informed consent even where a risk-benefit assessment is impossible.

39. One rationale for the position that the genetically unsuccessful may be worthy of special protections while those who are ill do not is that specific disease-causing genetic mutations may involve certain racial or ethnic groups. Supporters of protective legislation argue that it is necessary because the genetic tendency to disease is itself stigmatizing. Like the apprehension that racial prejudice creates a colour hierarchy in our society, one might worry about a genetic hierarchy. This is the main reason why genetic discrimination is different for other discrimination based on health issues. [20]

40. The tragic history of eugenics also casts a long shadow over contemporary claims regarding new knowledge about human genetics. We can argue that the justification offered by insurers for their use of genetic information in classifying risks is similar to that used in the earlier eugenics movement - that healthy people should not have to support people who have or may develop genetic diseases. The question we are considering is whether genetic discrimination expresses disrespect or unequal concern. The social meaning of genetic

discrimination, understood against this historical background, may well denigrate the equal value of people with genetic disease. Given the misuse of genetics in our past, this claim is surely plausible. [21]

41. The research on the human genome can enhance discrimination towards women. It was also emphasized that germ-line engineering would move choices about reproduction away from women, towards biotech corporations. Women would lose control of their own childbearing experiences. Despite these possible consequences of research on the human genome upon women, women are not participating in the decisions relating to the status of the research.

42. Indigenous peoples often denounce gene research as a form of biocolonialism. The indigenous communities who have evolved in relative isolation present the best prospect for grasping the variety of the human genome. Scientists have gathered and examined blood and tissue samples from hundreds of indigenous communities. Often these activities are carried out by biotechnology companies that expect to profit from this research, at the expense of indigenous communities. The research on the human genome can become another ground of discrimination against indigenous peoples.

43. People living in extreme poverty are among the first to be endangered by genetic manipulation. Their lack of means is correlated with a lack of information relating to the question of free consent in genetic manipulation. Often, people can be tempted to participate in the genetic experiments by rewards offered by the companies.

44. Given the possible dimensions of discrimination in the field of genetics, which is different from discrimination in the field of health, the author considers that this is an important area to be tackled by the further studies in the field.

IV. INTELLECTUAL PROPERTY RIGHTS AND THE HUMAN GENOME

45. A debate on the scope of protection for intellectual property is taking place between developing and developed countries. The former view the latter as demanding payment for imported technology that developing countries cannot afford. Innovations in the developing world have often been considered the traditional knowledge of the society, rather then subject matter eligible for patenting.[22]

46. Also, intellectual propriety rights would establish a monopolistic position on human genes. As a result, patent protection for human genes would discourage medical innovations and would inhibit advances in medicine. The response is that some developments in medicine would never have taken place without the incentive given by patent protection.

47. The most advanced countries in genomic research do not have the same standards: there are different standards in the United States, Europe and Japan, the principal States involved in human genome research. In Japan, for instance, it is required for an invention to have occurred in a non-natural way; also, all the processes in which the human body is an indispensable element are excluded from patenting.

48. The United States Code states "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title". The United States Patent and Trademark Office and courts have been expanding patent protection to cover isolated parts of human genes.

49. The substantive requirements for patentable subject matter under the European Patent Convention (EPC) are also different than the statutory requirements which must be met under Japanese and United States law. The substantive requirements under EPC are: (i) novelty; inventive step; and (ii) industrial application. Under the Convention, an invention is patentable if it is susceptible of industrial application, is new and involves an inventive step (art. 52.1). In addition, there are certain exceptions to patentability which are specifically important to the field of biotechnology. The exceptions illustrate the once conservative view on Euro-biotech patenting, as article 53 (a) leaves open an exception for inventions that violate public policy or morality. Further, article 53 (b) prohibits patents on biological methods for the production of plants or animals.

50. A Directive on the Legal Protection of Biotechnological Inventions was adopted by the EU in 1998 (98/44/EC). The initial purpose of the Directive was to ensure certainty and uniformity in patent protection of biotechnological inventions and to encourage European inventions in this field. The exceptions to patentability are where exploitation would be contrary to public policy or morality, such as processes for cloning human beings, processes for modifying the germ-line identity of human beings and the use of embryos for industrial or commercial purposes. The Directive allows the patentability of a sequence or partial sequence of genes which were isolated from the human body or otherwise produced by means of technical processes, provided that the criteria of novelty, inventiveness and industrial applicability are also satisfied. The Directive stipulates that the simple discovery of a sequence or partial sequence of a gene, as opposed to its isolation, cannot constitute a patentable invention. [23]

51. The language of the Directive leaves a lot of uncertainty, especially in connection with patent legislation. In order to better understand article 53 and its relationship to evolving biotechnology patent laws in Europe, an overview of conflicting case law must be discussed.[24] For example, under the Directive, a transgenic plant developed by Plant Genetic Systems would be patentable. Upon the Directive's adoption, many of its rules were contrary to the more conservative view of biotechnology patents as seen in the EPC, yet it did not cause States parties to EPC to circumvent their obligations under the Convention. On 16 June 1999, a decision by the Administrative Council of the European Patent Organization amended the Implementing Regulations to the EPC, which reflected the initiative of the Directive.[25] The Directive was contested at the European Court of Justice.[26]

52. At the international level patents in the field of the human genome is regulated by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO). The preamble to the TRIPS Agreement states the general goals of the Agreement, which include the reduction of distortions in the impediments to international trade and the promotion of effective and adequate protection of intellectual property rights, and the assertion that these measures and procedures to enforce intellectual property rights do not become barriers to trade.

53. For each type of intellectual property covered, TRIPS defines the subject matter covered, identifies the rights conferred, and sets the minimum duration of protection. Member countries may give more extensive coverage than is required by TRIPS. Each member country must give nationals of other members treatment no less favourable than it gives its own nationals concerning intellectual property protection. Any advantage given to a national of any country shall immediately and unconditionally be given to nationals of all other members. In order to be eligible for patent protection, an innovation must constitute an invention, has to be novel, non-obvious and useful. The gene sequence constitutes a discovery of a substance occurring in nature, rather than a novel and non-obvious invention.

54. Article 27.2 of TRIPS allows members to exclude from patentability inventions whose commercial use would jeopardize the public order or morality. The article allows members to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans and animals. The article provides for the possible exclusion from patentability of certain innovations in order to protect human, animal or plant life or health other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes. Article 27 is currently under review in the TRIPS Council. The vague wording of the exceptions leaves plenty of room for contradictory interpretations regarding the patentability of human genes.

55. Article 31 of TRIPS stipulates the conditions under which members of WTO may grant compulsory licensing, i.e. licences to physicians, researchers and others to use a patented gene sequence without the patent holder's permission, for a reasonable fee paid to the patent holder. Laboratories would be able to undertake genetic diagnostic testing and possibly discover new mutations. Pharmaceutical companies would not be able to prevent pharmacogenomic testing related to their products and research on gene therapies would be stimulated. For example, if a company had a specific patent on a gene or sequence, then that company would receive a portion of the profits when the specific gene or sequence they discovered was used in a mass-market drug. This is a feasible alternative because future drugs are likely to work because they influence the behaviour of many genes. Cross-licensing[27] agreements would still make profits attainable and thus incentive high, while also allowing crucial information to be shared in order to promote disease research. [28]

56. Sub-Commission resolution 2000/7 promises to throw a bigger spotlight on the human rights impact of the TRIPS Agreement. It declared that "since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food, and the right to self-determination, there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other hand".

57. It was considered that the argument regarding the influence of TRIPS on public health has shaped a noteworthy change in trade politics. At Doha, the Third WTO Ministerial Conference adopted a "Declaration on the TRIPS Agreement and Public Health" in which the ministers stressed the need for the TRIPS Agreement "to be part of the wider national and international action" to address public health problems. The Declaration asserts that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all".[29]

58. Despite the principles adopted at Doha nothing has been modified in a substantial way with respect to TRIPS and health, special and differential treatment and implementation-related issues and, more recently, in the areas of agriculture and market access for non-agricultural products. The health area is considered to be one of the most important failures of the post-Doha WTO. The question of TRIPS and genetics remains an area that was not given a proper answer by WTO, and especially the TRIPS regime.

59. The Convention on Human Rights and Biomedicine does not deal explicitly with the patentability of human genes. It stipulates in article 12 that "the human body and its parts, shall not, as such, give rise to financial gains". In Parliamentary Assembly recommendation 1425 on biotechnology and intellectual propriety, human-derived genes can neither be considered as inventions, nor be subject to monopolies granted by patent.

60. Another potential way to deal with the problems created by gene patents is to create a greater opportunity for third-party challenges to the grant of a patent. Some commentators advocate expanding the existing procedure within the patent office whereby any third party can ask for a patent to be re-examined. Measures to ensure greater scrutiny of patents could include greater participation of third parties in the initial interviews about a patent application, and the chance for third parties to appeal patent office re-examination decisions. This would allow, for example, organized patent groups to have their interests represented in the decisions about the granting of gene patents.

61. But allowing those persons from whom genes are taken to have a property interest in the patent is not a comprehensive solution to the problems created by gene patents. It will be an extremely rare case where researchers will actually need to negotiate with the people who have a gene mutation associated with a particular disease or their family members. For common complex genetic diseases, such as heart disease, so many people will have a particular mutation that researchers will likely be able to find research subjects who will not insist on participating in the patent application. Moreover, for most diseases, researchers will not have to collect DNA from people in the first place. Researchers will be able to use DNA samples that already exist in hospital pathology laboratories, public health screening programmes, research centres, and DNA banks.[30]

V. CONCLUSIONS AND RECOMMENDATIONS

62. **An international framework should be developed, taking into account the public but also the private research in the field. Individual rights and the broader social context should be understood as interwoven and reciprocal. Enforceability has to be combined with a soft-law framework. National codes could specify the criteria for deciding whether a new genetic test should be marketed, used, or even developed at all. A bioethics commission would clear tests and therapies for ease of use in the market. In this way, the availability of genetic tests and therapies could be limited only to those that have immediate and real benefits for individuals' health. Tests and therapies would not be used in insurance or employment contexts. Rules should also be established to govern the disclosure of genetic information to third parties. Codes for genetic counselling could also be established to help individuals make choices regarding their particular circumstances. If at all possible, genetic counselling should be obtainable for all persons, irrespective of their social and economic resources.**

63. **All the solutions have to take into account the role of the private sector in the genomic industry. Biotechnology has become more and more private. It involves both State and non-State actors. Any legal framework that targets only intergovernmental relationships cannot adequately regulate human genomics. It is important to create a transnational forum for biotechnologies.**[31] **Numerous NGOs are interested in transnational biotechnology. There are sound arguments in favour of engaging all parties through voluntary structures while at the same time imposing a coercive regime. The speed with which technology is developing argues in favour of using soft-law instruments in more effective ways. Enforcement remains fundamental, as hard law is in international law. Human cloning has to be very severely punished by the criminal codes of States and, given the danger implied by genetic manipulation to the human species, characterized as a massive violation of human rights.**

64. **Although Governments may introduce regulation, it will largely be private actors such as corporations and physicians who will implement the regulations. A regulatory scheme, therefore, should permit horizontal suits that enable people to sue other private actors to enforce State regulation. Horizontal suits would help dismantle the public and private distinction by subjecting the power arrangements and social ordering within the private sphere to scrutiny.**

65. **Given the number of discoveries in the field of genetics, it is very important that States promote access to reliable information. It is important that a public debate be launched and all the stakeholders - researchers, ethical experts, business circles - have to participate.**

66. **It is worth emphasizing the universal ethical principals which are the basis of fundamental human rights, such as individual dignity and value of the human life and respect for the individual. It is also valuable to reaffirm the necessity of safeguarding the freedom of science and research with the aim of benefiting all of humanity. At the same time, some redistributional principals have to be agreed in order to ensure that steps are taken in the direction of equal access to new therapies.**

67. **Predictive genetic tests may be performed only for medical purposes and everybody is entitled to the protection of their personal data. Discrimination against a person on the ground of his/her genetic heritage should be expressly prohibited. Discrimination in genetics is different from discrimination in other fields of the health regime.**

68. **It is worth taking into account the proposal to organize a world summit on the future of the human species to protect the integrity of the human species, to prevent the market and its powerful industries, businesses and self-serving scientists from deciding for us what the future of humanity is.**

Notes

[1] J. Habermas, On the way to liberal eugenics: the dispute over the ethical self-understanding of the species, colloquium at New York University, 2000. See also J. Habermas, *The Future of Human Nature*, Polity Press, 2003.

[2] S. Pridan-Franck, "Human-Genomics: A Challenge to the Rules of the Game of International Law", *Columbia Journal of Transnational Law*, vol. 40, 2002.

[3] Ibid.

[4] D. Shelton, "Globalization and the erosion of sovereignty: protecting human rights in a globalized world", *Boston College International and Comparative Law Review*, vol. 25, 2002.

[5] See E.S. Tenenbaum, "A World Park in Antartica: The Common Heritage of Mankind", *Virginia Environmental Law Journal*, vol. 10, 1990.

[6] The Human Genome Project is an international attempt to map and sequence the approximately 100,000 genes of the human body. The project consists of mapping and sequencing all chromosomes. It means determining the exact location of the DNA markers which act as signs to indicate where specific genes lie on each chromosome. S.M. Kirby, "The Human Genome Project-Promise and Problems", *Journal of Contemporary Health Law and Policy*, vol. 11, 1994; K. Smith and D.M. Kettelberger, "Patents and the Human Genome Project", *American Intellectual Property Law Association Quarterly Journal*, vol. 22, 1994.

[7] M. Sturges, "Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind", *American University International Law Review*, vol. 13.

[8] Instead, Belgium, France, Germany, Italy, Japan, the Netherlands, the United Kingdom and the United States developed and signed a Provisional Understanding Regarding Deep Seabed Matters in 1984, which expressed the understanding of and agreement among these countries concerning deep seabed mining.

[9] K. Zullo, "The Need to Clarify the Status of Property Rights in International Space Law", *Georgetown Law Journal*, vol. 90 (July 2002).

[10] M. Mariani, "Stem Cell Legislation: An International and Comparative Discussion", *Journal of Legislation*, vol. 28, 2002.

[11] The replication of organisms, plants and for agricultural purposes has been commonplace for many years. Similarly, cloning of certain animals, particularly for food production, has become commonplace, if not universally accepted. See Barry Brown, "Human Cloning and Genetic Engineering: The Case for Proceeding Cautiously", *Albany Law Review*, vol. 65, 2002; S. Murphy, "Biotechnology and International Law", *Harvard International Law Journal*, vol. 42, 2001.

[12] For the idea that uniqueness is not part of current international human rights law, see S. Marks, "Public Health and International Law: Tying Prometheus Down: The International

Law and Human Genetic Manipulation", *Chicago Journal of International law*, spring 2002: "This idea, like uniqueness and existential identity, may be emotionally appealing but is not part of current international human rights law".

[13] "With their loss the fundamental belief in human equality would also be lost. Of course, we know that the rich are much better off than the poor and that real equality of opportunity will require both universal education and income redistribution; nonetheless, the rich and powerful may not enslave, torture, or kill even the poorest human on the planet. Likewise, it is a fundamental premise of democracy that all humans, even the poor, must have a voice in determining the future of our species". See G. Annals, "The Man on the Moon, Immortality, and other Millennial Myths: The Prospects and Perils of Human Genetic Engineering", *Emory Law Journal*, vol. 49, No. 3, 2000.

[14] Ibid.

[15] Ibid.

[16] The proposed convention stipulates that States shall take action, including the adoption of criminal laws, to prohibit anyone from initiating or attempting to initiate a human pregnancy or other form of gestation using embryos or reproductive cells which have undergone intentional inheritable genetic modification. In G.J. Annas, L.B. Andrews and R.M. Isasi, "The Genetic Revolution: Conflicts, Challenges and Conundra: Protecting the Endangered Human: Toward an International Treaty Prohibiting Cloning and Inheritable Alterations", *American Journal of Law and Medicine*, vol. 28, 2002.

[17] A high-level group of experts, convened by the High Commissioner for Human Rights in January 2002, identified the issue of reproductive human cloning as a priority in the work of the High Commissioner in the area of human rights and biotechnology. The conclusions of the experts were attached as an annex to the report of the Secretary-General on human rights and bioethics submitted to the Commission on Human Rights at its fifty-ninth session (E/CN.4/2003/98).

[18] I.M.J. Smith, "Population-based Genetic Studies: Informed Consent and Confidentiality", *Santa Clara Computer and High Technology Law Journal*, vol. 57, 2001.

[19] A classic example of infringement of privacy and informed consent is the case of *Moore v. Regents of California*, in which Moore gave consent to blood tests and surgery but did not consent to, nor have knowledge of, the use of his cells to develop a profitable cell line. See 51 Cal.3d 120, 793 P.2d 479 (1990).

[20] See for a comprehensive description of the debate, D. Hellman, "What makes genetic discrimination exceptional?", *American Journal of Law and Medicine*, vol. 29, 2003.

[21] Ibid.

[22] S. Pridan-Franck, op. cit.

[23] Although this Directive was adopted by the European Parliament after 10 years of very hot debate, it is still controversial. Many EU member States are still reluctant to introduce the Directive into their domestic law when they should have done so in July 2000. As stated by Noëlle Lenoir, this debate is the more interesting as it illustrates how the respect of the human body and the principle of its non-commercialization are intermingled with economic and social concerns.

[24] Case law discussing article 53 issues in the past has been somewhat contradictory. This disagreement has been particularly apparent in the field of transgenics. A comparison of the well-known Harvard mouse case, a transgenic animal case, and *Plant Genetic Systems v. Greenpeace*, a case concerning transgenic plants, illustrates the contradiction.

[25] For example, the decision added a chapter entitled "Biotechnological Inventions" which included general definitions, the scope of biotechnological inventions, clarifications of article 53 exceptions and information on patenting the human body and its elements, including genes. These additions to EPC reflect the initiative of the Directive and therefore demonstrate the reality of European patent law evolution.

[26] In June 2001, Advocate General Jacobs delivered his opinion which stipulated that the Directive does not confer on patent holders the right to ownership of isolated genes and that the right to patent protection is restrained by sufficiently clear limitations; the Directive does not view the human body as an instrument eligible for ownership and does not violate human dignity.

[27] The European Union also provides for compulsory licensing of patented inventions under certain circumstances to prevent the abuses that can result from the exclusive rights granted under a patent.

[28] L.B. Andrews, "The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs", *Houston Journal of Health Law and Policy*, vol. 65, 2002.

[29] S. Charnovitz, "WTO Cosmopolitics", *New York University Journal of International Law and Politics*, vol. 34, 2002.

[30] Ibid.

[31] See S. Murphy, op. cit.
