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Genetic Resources, Biotechnology  
and Human Rights:  
The International Legal Framework

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## **Abstract**

As with any rapid technological developments, the biotechnology revolution is putting great strains on the law and its ability to adapt to new realities and challenges. One particularly pressing need is to assess the role that international law and especially international human rights have in developing a generally acceptable framework of regulation in this area. This paper aims at identifying principles and norms of international law that can support this task. It shows that control over genetic resources cannot be linked to a single normative model but depends on the nature and location of the resources; it highlights the notion of the common interest of humankind in the access to and utilization of genetic resources. It concludes with an inventory of the relevant human rights that should guide states and the international community in developing regulatory schemes that may be capable of reconciling the legitimate goal of scientific and technological innovation with the safeguard of human dignity. This paper will be published as the introductory chapter in Francesco Francioni (ed.) *Biotechnology and International Human Rights*

## **Keywords**

International law - International human rights - United Nations – UNESCO - Bioethics



# GENETIC RESOURCES, BIOTECHNOLOGY AND HUMAN RIGHTS: THE INTERNATIONAL LEGAL FRAMEWORK

Francesco Francioni

## 1. Introduction

Is it useful to study the interaction between developments in biotechnology<sup>1</sup> and international human rights? After all, isn't science<sup>2</sup> constantly expanding the limits of human freedom and thus compelling us to re-define the substance and scope of such rights? How relevant can it be to look at the present challenges and dilemmas posed by relentless advances in biotech science through the lens of a fixed catalogue of human rights? Is a human rights approach, and indeed a law-based approach, capable of bridging the gap between fundamentally divergent ethical views in this area?<sup>3</sup>

These are not easy questions, and the reflections we have developed in these collected essays do not aim at providing a uniform and definitive set of answers. On the contrary, the approach taken through the lens of human rights is pluralistic and aimed at identifying a broad range of perspectives in which biotechnology regulation can be placed.

But even from the view point of human rights, an evaluation of the impact of biotechnology on international law requires a plurality of epistemological approaches and different levels of inquiry. At a first level, one needs to start with the acknowledgment of the widespread perception that the new genetic science is placing peoples in the difficult position of facing "something unknown", of not fully grasping the risks and social implications involved in the contemporary process of developing new biotech products and services. In this context, a human rights approach based on transparency, information and participatory rights can contribute to people's empowerment and to raising the awareness of their individual and collective entitlements *vis-à-vis* the blind power of science and industry.

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<sup>1</sup> For the sake of convenience the term 'biotechnology' is used in this essay in accordance with the definition provided in the *Convention on Biological Diversity* (see <<http://www.biodiv.org/doc/legal/cbd-en.pdf>>): as any technological application that uses biological systems, living organisms, or derivatives from them, in order to make or modify products or processes for specific use.

<sup>2</sup> The term 'science', as used in this chapter, is inclusive of hard science, soft science, technology, engineering and medicine, taking into account the definition provided by UNESCO in 1974 as an enterprise wherein humankind "... acting individually or in small or large groups, makes an organized attempt, by means of the objective study of observed phenomena, to discover and master the chain of causalities; brings together in a co-ordinated form the resultant sub-systems of knowledge by means of systematic reflection and conceptualization ... and thereby furnishes itself with the opportunity of using, to its own advantage, understanding of the processes and phenomena occurring in nature and in society". See *UNESCO Recommendation on the Status of Scientific Researchers*, 18 C/ Res. 40, November 1974.

<sup>3</sup> On the limits of law as a regulatory modality in relation to new technologies, see the fundamental contribution of Stanford professor L. Lessig, *Code and other Laws of Cyberspace*, New York, 1999.

At another level of analysis, looking at biotechnology through the lens of human rights will immediately entail the acknowledgment of the basic freedom of scientific research and the right “to enjoy the benefits of scientific progress and its applications”, to use the words of article 15 of the International Covenant on Economic Social and Cultural Rights. But at the same time this freedom and this right are not absolute. They must be balanced against certain standards of bioethics whose respect is a condition of the legitimacy of the claim to freedom of scientific research.<sup>4</sup> On this point, one may argue that ethical standards are always responsive to religious and cultural specificity. That is true. But precisely because of that resort to international human rights norms is capable of providing a set of common, objectively defined values, inasmuch as they reflect the universally shared values of respect for life, liberty, human dignity and non-discrimination and, possibly, more specific societal values such as the right to information and of participation in policy decisions, and the right to share in scientific advancement and its benefits.<sup>5</sup> At the same time, internationally recognized human rights, represent the benchmark against which public authorities and international institutions can measure the legitimacy of policy choices or of specific decisions relating to the application of modern science. This aspect is especially relevant in the field of biotechnology. Contrary to the old-fashioned view that human rights depend on states doing nothing, i.e., non interference with individual autonomy, in this field governments have positive obligations to intervene in the sphere of scientific, technological and economic activities in order to ensure that freedom of research and market freedoms are not abused or distorted in such a way as to cause adverse effects on human rights. This function is consistent with the general provision of Article 28 of the Universal Declaration of Human Rights,<sup>6</sup> which, by laying down the right to a “social and international order where the rights and freedoms set forth in this Declaration can be fully realized”, calls upon governments to take positive steps toward the development of a social structure in which human rights can take root and be safeguarded.<sup>7</sup>

At a technical-legal level, a reason for studying the interplay between human rights and biotechnology is that scientific and technological advances have always had the effect of stimulating the development of new law, both in domestic societies and in international law. Thus, it is important to understand what role human rights have in the dynamic evolution of the law. The development of modern biotechnologies, has spurred the elaboration of a considerable number of treaties and soft-law instruments designed to establish standards and oversight procedures in relation to biotechnology related risks. At the global level, the Cartagena Protocol on Biosafety was adopted in response to concerns that modern biotechnology may have adverse impacts on biodiversity.<sup>8</sup> To this end, it provides for stringent risk assessment of “living modified organisms” and for advance consent by the importing state pursuant to a broad interpretation of the precautionary approach. In the field of agriculture, the 2001 Food and Agriculture Organization (FAO) Treaty on Plant Genetic Resources has established a framework of international cooperation for the conservation and sustainable use of plant genetic resources for food and agriculture,<sup>9</sup> based on the recognition

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<sup>4</sup> On the question of how international human rights may support ethics in scientific research, see F. Francioni, “Valori etici e diritto internazionale”, *Rivista di Studi Politici Internazionali* (2004), p. 567 ff.

<sup>5</sup> See article 27 para. 1 of the *Universal Declaration of Human Rights*, *infra*, note 6.

<sup>6</sup> See U.N. A.G. Res. 217A (III), 1948; U.N. Doc. A/810 (1948).

<sup>7</sup> See article 28.

<sup>8</sup> See 2000 *Cartagena Protocol on Biosafety*, available at <<http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf>>

<sup>9</sup> See 2001 *International Treaty on Plant Genetic Resources for Food and Agriculture*, available at <<ftp://ext-ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf>>

of the sovereign rights of States over their phyto-genetic resources and on the principle of “facilitated access” and “sharing of benefits” arising from the scientific and commercial use of such resources.<sup>10</sup> Concern with biodiversity conservation and with the risk posed to the environment by the deliberate release of genetically modified organisms has had repercussions also on regional international law. Of special relevance in this respect is the EU Directive of 12 March 2001,<sup>11</sup> establishing a common system of authorization and oversight of the deliberate release of genetically modified organisms into the environment, as well as of the placement of such organisms or their products on the market. In Latin America, the increasing practice of bio-prospecting has spurred legislation and administrative practices aimed at regulating access to local biological material and at ensuring a fair distribution of benefits derived from their use and commercialization. Notable in this regard are Decisions 391 of 1996 and 523 of 2002 adopted by the Andean Community Commission with the objective of laying down conditions for access to the rich genetic patrimony of the region.<sup>12</sup> These Decisions are informed by the principle of benefit-sharing and the objective of capacity-building in the interest of the Andean countries.<sup>13</sup>

All these instruments are motivated by two distinct but interrelated sets of concerns: protection of the environment, faced with insufficient knowledge of the long term effects of genetically modified organisms on natural ecosystems; and the creation of a system of just distribution of benefits arising from the use and commercialization of genetically engineered material and its products. This second concern is of particular relevance for developing countries: first, because they are the most important repository of biological diversity and, consequently, of potentially useful genetic material; secondly, because they are resisting the development of an international legal regime based on the principle of freedom of access or of common heritage of genetic resources, which they fear – not without good reason – would leave them at the margins of the biotechnology revolution. These concerns are part of the complex dialectic between industrial countries and less-developed ones. However, the problems arising from this complex relationship have not yet been articulated in the language of human rights, but rather in the more elusive language of “sustainable development” and “equitable sharing of benefits”. As we shall see in the course of this chapter, collective rights, such as self-determination and peoples’ sovereign right over natural resources, as well as individual and community rights, may provide a more precise and sound basis for the development of international law in the area of biotechnology regulation.

A closer relationship between the development of biotechnology and human rights can be found in a number of international instruments adopted in the last fifteen years in the field of biotechnology applied to human genetic resources. At the global level UNESCO has been at the forefront of an ambitious programme aimed at setting legal and ethical standards applicable to the human genome. The results of this programme are, for the time being, four important soft law instruments: the 1997 Universal Declaration on the Human Genome and Human Rights (UDHG),<sup>14</sup> the 1999 Guidelines for the Implementation of such Declaration,<sup>15</sup>

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<sup>10</sup> See articles 10-13.

<sup>11</sup> See Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council directive 90/220/EEC – Commission Declaration, *O.J.* L 106 of 17 April 2001, p. 1 ff.

<sup>12</sup> The two decisions are available, respectively, at <<http://216.15.202.3/docs/andeancommunity-decision391-1996-en.pdf>> and at <<http://www.comunidadandina.org/ingles/treaties/dec/D523e.htm>>

<sup>13</sup> See F. Novak, “Biotechnology and Regional Integration Systems: Legislation and Practices in the Andean Community Countries”, in Francioni and Scovazzi “Biotechnology and International Law”, Oxford, Hart publ. 2006. .

<sup>14</sup> See *Universal Declaration on the Human Genome and Human Rights*, 11 November 1997, available in the UNESCO Web site, at <<http://www.unesco.org>>



and the 2003 International Declaration on Genetic Data and the 2005 Universal Declaration on Bioethics and Human Rights (UDBHR).<sup>16</sup> The UN General Assembly endorsed the UDHG in 1998<sup>17</sup> and in the past three years has been engaged in the negotiation of a new convention designed to restrict human cloning.<sup>18</sup> At the regional level, the Council of Europe has, since 1997, adopted a variety of legal instruments setting ethical standards in the field of biomedicine and biomedical research, including the Oviedo convention on human rights and biomedicine,<sup>19</sup> the additional protocol on the prohibition of human cloning,<sup>20</sup> the 2002 Additional Protocol on transplantation of organs and tissues of human origin,<sup>21</sup> and the 2005 Additional Protocol on biomedical research.<sup>22</sup>

Against the background of this international legislation, and building on the plurality of legal perspectives outlined above, this paper will follow a three step analysis. First, it will try to identify the competing entitlements – property rights, sovereignty, common heritage – that present international law recognizes over genetic resources and their use, including their exploitation through biotechnology applications. Second, it will focus on the general interest that humanity as a whole has in the conservation and management of genetic resources and in the regulation of related biotechnology. Third, it will try to outline a core of international human rights whose respect should be considered a condition *sine qua non* for the legitimate exercise of the freedom of science and business in the development and application of modern biotechnology.<sup>23</sup>

## 2. Sovereign rights and bio-genetic resources.

Central to the discussion on how modern biotechnology affects international human rights is the identification of who has rights over the genetic resources that form the raw material from which biotechnology develops new products and new processes. A fundamental distinction in this respect is necessary between plant and animal genetic resources on the one hand and the human genome on the other. While the latter is covered by

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<sup>15</sup> See C/Resolution 23 of 16 November 1999, endorsing the guidelines for the implementation of the Universal Declaration on the Human Genome and Human Rights.

<sup>16</sup> The *International Declaration on Human Genetic Data*, was adopted on 16 October 2003, and the *Universal Declaration on Bioethics and Human Rights* on 19 October 2005. Both are available in the UNESCO Web site, at <<http://www.unesco.org>>

<sup>17</sup> See A/RES/53/152 of 9 December 1998.

<sup>18</sup> See the draft text addressed to the U.N. Secretary General by the Government of Costa Rica on 2 April 2003, U.N. doc. A/58/73 of 17 April 2003.

<sup>19</sup> See *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*, Oviedo, 4 April 1997, CETS n. 164.

<sup>20</sup> See *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*, Paris, 12 January 1998, CETS n. 168.

<sup>21</sup> See *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin*, Strasbourg, 24 January 2002, CETS n. 186.

<sup>22</sup> See *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research*, Strasbourg, 25 January 2005, CETS n. 195.

<sup>23</sup> Of course, in this analysis one cannot ignore that modern genetic science produces a new form of technological power very different from that exercised by the State and to which traditionally human rights abuses are related. On this aspect see WEERAMANTRY(ed.), *Human rights and scientific and technological development*, United nations university press, Tokyo, 1990

conventional human rights law and by specific soft law instruments – to be examined later –, the former, insofar as they belong to the natural environment, may be brought under the general rule of international law according to which the physical space of the world is allocated to national spheres of jurisdiction coinciding with the territory of a given State. Counterparts of this rule are the regime of the high seas,<sup>24</sup> where no sovereignty is recognized and freedom of access is guaranteed to all states, and the special regime of the common heritage of humankind that has emerged with regard to the international seabed area.<sup>25</sup> If we leave these exceptions aside for the time being (they shall be dealt with in section 3.), the question we must address is the following: is the principle of sovereignty and in particular the post-colonial principle of “permanent sovereignty” over natural resources applicable to plant and animal genetic material that constitutes the object of biotechnology investigation and commercial application? This question is preliminary to any further discussion of the right of access to genetic material because there is a fundamental distinction between natural resources understood as minerals or as biological resources whose utilization entails depletion and consumption in the course of economic activities, and bio-genetic resources whose *genotype*, rather than *phenotype*, is targeted for sampling and biotechnological application with negligible impact on the environment. This distinction, although well-founded in science, has not fit comfortably into existing categories of international law. At the beginning, in the early 1980s, recognition of the enormous potential of modern biotechnologies for agriculture led the FAO to proclaim that plant genetic resources are an exception to the principle of permanent sovereignty, insofar as they constitute, by their very nature, part of the common heritage of humankind. The International Undertaking on Plant Genetic Resources adopted in 1983<sup>26</sup> recognized that plant germoplasm is a public good of economic and social value to be “explored, preserved, evaluated and made available for plant breeding and scientific purposes”<sup>27</sup> consistent with “*the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction*”.<sup>28</sup> In spite of this unambiguous recognition of plant genetic resources as part of humanity’s collective genetic estate, subsequent developments in international law have fallen short of implementing the principle of the common heritage of humankind with respect to this type of resource. In sharp contrast to developments in the law of the sea – which led to the implementation of the principle of the common heritage of humankind with respect to the mineral resources of the deep seabed – the FAO gradually departed from its initial position and progressively turned toward a cautious recognition of “sovereign rights” as a legal model to regulate the exploration and development of genetic resources.<sup>29</sup> This legal *revirement* was undoubtedly influenced by the objective difficulty of developing, within the structure of the FAO, effective institutional mechanisms capable of managing the principle of the common heritage of humankind;<sup>30</sup> but it was also related to the major change of policy perspective introduced by the negotiation and subsequent adoption of the Convention on Biological

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<sup>24</sup> See 1982 *United Nations Convention on the Law of the Sea*, UNTS, vol. 1833, p. 397, part VII.

<sup>25</sup> *Ibid.*, part XI.

<sup>26</sup> See FAO Res. 8/83, Rome, 1983, available at <<ftp://ext-ftp.fao.org/cgrfa/Res/C8-83E.pdf>>

<sup>27</sup> See article 1.

<sup>28</sup> *Ibid.* (emphasis added).

<sup>29</sup> See the amendments of the Undertaking by subsequent “agreed interpretations” in 1989 (Res. 4/89, available at <<ftp://ext-ftp.fao.org/cgrfa/Res/C4-89E.pdf>>; Res. 5/89, available at <<ftp://ext-ftp.fao.org/cgrfa/Res/C5-89E.pdf>>) and 1991 (Res. 3/91, available at <<ftp://ext-ftp.fao.org/cgrfa/Res/C3-91E.pdf>>). See M. Footer, “Agricultural Biotechnology, Food Security and Human Rights”, in Francioni and Scovazzi (eds) “Biotechnology and International Law”, cit. ; and F. Francioni, *International Law for Biotechnology*, *ibid.*

<sup>30</sup> See Footer, *cit.*, note 29.

Diversity.<sup>31</sup> This convention, while proclaiming in its preamble that biodiversity constitutes “a common concern of humankind”, explicitly recognized in Article 3 that “States have ...the sovereign right to exploit their own resources ...”. This provision was reinforced by Article 15, which recognizes that access to genetic resources is subject to “...the sovereign rights of States over their natural resources” and that “the authority to determine access to genetic resources rests with the national government and is subject to national legislation”. Since the entry into force of the biodiversity convention in 1993, the paradigm of “sovereign rights” over biological resources, including genetic resources, has influenced negotiations within the FAO for the adoption of a multilateral framework of facilitated access and benefit sharing as regards genetic resources important for agriculture. The so called Seed Treaty adopted by the FAO Conference in 2001<sup>32</sup> has clearly followed a sovereignty-based approach towards access to, and exchange and exploitation of, genetic material. Thus, it has departed from the initial common heritage approach embraced in the 1980s.

Read against the background of this evolving practice, the question we raised at the outset – *i.e.* whose rights are involved in the governance of biotechnologies – prompts a preliminary answer: at least with regard to plant genetic resources and by analogy animal genetic resources found within state territory, national governments and non-state actors involved in the development of relevant international law have not accepted the application of the principle of the common heritage of humanity. Instead, they have preferred to follow the established sovereign rights approach, which guarantees their role as gate keepers in this new possible field of economic development. This practice must be taken into account in assessing the role that human rights play in the regulation of genetic resources and biotechnology. In the field of biogenetic resources for agriculture, international law still recognizes the central role of the State as source of authority and of regulation of access and economic utilization of resource related activities. Naturally, States are free to transfer their authority, or if we prefer their “sovereign rights”, to international organizations, as in the case of the EU. But this means only that the identification of human rights involved in biotechnology governance will need to take place in the context of powers (and regulatory competence) transferred to an international or supra-national organization. In the case of the EU this task is facilitated by the existence of a specific “charter of rights”, now incorporated into the Constitutional Treaty.<sup>33</sup>

### 3. Community Interests and Rights.

#### 3.1 The Human Genome

In sharp contrast to the re-assertion of sovereign rights over bio-genetic resources relevant to food and agriculture, human genetic resources – the subject of investigation and application in medicine and pharmacology – have increasingly been perceived as part of the common heritage of humanity. As such, they are not deemed to fit the category of “natural resources”, so as to fall within the “sovereign rights” of the territorial state. As is known, developments in this field are due mostly to the ground-breaking research done in the last decade to complete the so-called mapping of the human genome. The results achieved thus far open possibilities of application of gene technology to the life sciences, with the promise

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<sup>31</sup> See *supra*, note 1.

<sup>32</sup> See Resolution 3/01 of the FAO Conference, available at <[http://pgrc3.agr.gc.ca/itgrfa/conference\\_e.html](http://pgrc3.agr.gc.ca/itgrfa/conference_e.html)>; (see *supra*, note 9).

<sup>33</sup> See further the chapter by Righini in this volume.

of improving the health, longevity and welfare of many human beings. At the same time, the prospect of biotechnological applications to human genetic material has raised justifiable fears that human beings may be reduced to “means” as a function of biological experimentation and possibly of commercial utilization of the knowledge derived from the former.<sup>34</sup> Against this problematic background, international practice has, in less than ten years, evolved toward the robust affirmation of human rights standards that rest on the extension of the principle of common heritage of humankind from the domain of resources to the new concept of the human genome. Thanks to the vigorous effort of UNESCO, whose mandate in the field of science and culture is linked to the guarantee of “the democratic principle of the dignity, equality and mutual respect of men”,<sup>35</sup> the UDHG was adopted in 1997.<sup>36</sup> Article 1 of the Declaration states 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. In a symbolic sense, it is the heritage of humanity”. The use of the qualifying phrase “in a symbolic sense” has been understood as weakening the legal strength of this article.<sup>37</sup> However, a more convincing explanation is that the adjective ‘symbolic’ is rather intended to stress that the human genome is not to be treated in a patrimonial sense, as the mineral resources of the sea bed, and that it is not subject to forms of individual or collective appropriation.<sup>38</sup> Its value for humanity is thus not so much in its potential to yield economic benefits, as is the case for the tangible natural resources to which the same concept had been previously applied,<sup>39</sup> but rather in its reflexive capacity to establish an ethical obligation, owed to humanity as a whole, to preserve and safeguard the continuity of the human species when faced with the unfathomable applications of biotechnologies to human genetic engineering. This interpretation is buttressed by the general context of the Declaration, which conclusively confirms an intention to proclaim the human genome the common heritage of humanity. The Preamble of the Declaration rejects any manipulation of the human genome for social and political purposes in a manner that is incompatible with the inherent human dignity of all “members of the human family”.<sup>40</sup> Article 4 provides that the human genome in its natural state shall not give rise to financial gains. This makes the human genome an asset *extra commercium*, not subject to appropriation and patenting in its natural form. Article 10 obligates scientific genomic research in biology and in medicine to respect human dignity and the fundamental rights of individuals and peoples. Further, the Declaration requires a commitment to international cooperation in the assessment of risks and benefits deriving from genomic research and in the

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<sup>34</sup> See Lenzerini, *Biotechnology, Human Dignity and the Human Genome* in Francioni and Scovazzi, (eds) “*Biotechnology and International Law*”, cit. note 13, and Boussard in this volume

<sup>35</sup> See the UNESCO Constitution, available at <<http://www.unesco.org>>, Preamble and article 1.

<sup>36</sup> See *Universal Declaration on the Human Genome and Human Rights*, 11 November 1997, available in the UNESCO Web site, at <<http://www.unesco.org>>

<sup>37</sup> Pavoni . in Francioni and Scovazzi (eds) cit note 13.

<sup>38</sup> See L. Sturges, “Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind”, 13 *American University International Law Review*, 1997, 219, p. 249; Lenzerini, *cit.*, note 34.

<sup>39</sup> See Part XI of the 1982 Law of the Sea Convention, *supra*, note 25; see also the 1979 *Agreement Governing the Activities of States on the Moon and Other Celestial Bodies*, U.N. G.A. Res. 34/68 (1979), available at <[http://www.lunarregistry.com/treaties/treaty\\_1979.shtml](http://www.lunarregistry.com/treaties/treaty_1979.shtml)>

<sup>40</sup> See Preamble, para. 4, which states “... the recognition of the genetic diversity of humanity must not give rise to any interpretation of a social or political nature which could call into question ‘the inherent dignity and ... the equal and inalienable rights of all members of the human family’, in accordance with the Preamble to the Universal Declaration of Human Rights”.

promotion of developing countries' capacity to carry out such research and to benefit from its technological applications.

Obviously, the UDHG is not a binding treaty. Its text can at best be understood to reflect emerging principles of international law which, though expressed in the soft-law form of the Declaration, are designed to model the evolution of customary law and to eventually harden into more detailed and exacting standards. In any event, it is difficult to deny that the Declaration has already affected the *opinio iuris* of the international community. Its text emanates from the UNESCO General Conference, a body of universal character, where States can express their opinion and cast their vote. Its adoption by acclamation was preceded by extensive consultations and technical preparatory work, with the participation of civil society and the epistemic community, with its scientific, legal, ethical components. No objections or reservations were put on the record at the time of its adoption. After its adoption, the UN General Assembly endorsed its text by Resolution of 9 December 1998.<sup>41</sup> Further, the Universal Declaration has not remained an isolated act. In 1999 UNESCO adopted a resolution adopting implementing measures designed to facilitate the interpretation and application of the Declaration in domestic law.<sup>42</sup> In October 2003 the General Conference adopted the International Declaration on Human Genetic Data,<sup>43</sup> a document that confirms the status of the human genome as the common heritage of humanity.

All the documents discussed above have received broad support from the international community. In 2005 they provided the necessary background against which UNESCO adopted the UDBHR. Most importantly, they are providing principles and criteria which regional organizations and domestic legal systems are drawing upon in drafting legislation and codes of ethics for the exploration and use of the human genome consistent with its nature as a public good.

### 3.2 Bio-Genetic Resources in Common Spaces.

Can the principle of common heritage play a role beyond the human genome? Can it provide a normative model, in certain circumstances, for the regulation of plant and animal genetic resources also? These questions arise because, although most genetic resources are located in areas subject to national jurisdiction, biotechnology research and industry is increasingly attracted by the genetic material found in organisms that have developed in spaces beyond national jurisdiction – such as the deep sea and Antarctica.<sup>44</sup> There is no state sovereignty in these areas, or at least no generally recognized sovereignty; therefore, there cannot be any uncontested “sovereign right” within the meaning of section 2 of this chapter. A lack of such a right does not, however, entail that the applicable regime must necessarily be that of common heritage. An alternative model could be that of freedom, as is applicable to the high seas and comparable spaces beyond national jurisdiction. Two arguments might support the application of the principle of freedom in these areas. The first is the close analogy of genetic prospecting and development with fishing, which is one of the classic freedoms of the high seas.<sup>45</sup> The second argument is that bio-prospecting is a manifestation of scientific research, which is also subject to the regime of freedom under customary

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<sup>41</sup> See *supra*, note 17.

<sup>42</sup> See *supra*, note 15.

<sup>43</sup> See *supra*, note 16.

<sup>44</sup> See T. Scovazzi, “Bioprospecting on the Deep Seabed: A Legal Gap Requiring to Be Filled”, in Francioni and Scovazzi (eds) “Biotechnology and International Law”, cit. as well as Viigni, “Bioprospecting in Antarctica: The Economic Value of a Natural Reserve”, *ibid.*; and . Guyomard, “Bioprospecting in Antarctica: A New Challenge for the Antarctic Treaty System”, *ibid.*

<sup>45</sup> Scovazzi, 1979

international law and under the 1982 Law of the Sea (LOS) Convention.<sup>46</sup> However, these arguments are not conclusive. In our view, exploration and collection of genetic material in areas beyond national jurisdiction cannot be assimilated to fishing. Fishing consists of harvesting biological resources for human consumption, or agricultural or commercial use, and has no relation to the identification and possible technological development of the intangible genetic patrimony contained in living organisms. Freedom to fish entails freedom for the fisherman to appropriate, process and sell the catch, on the assumption that the resources in question are renewable and that, accordingly, anyone can have access to them as long as the equal freedom of others is respected. In the case of genetic resources it is the genetic information contained in the targeted living organism that is at stake. Access to such information does not necessarily entail automatic appropriation of the knowledge that will form the basis of biotechnological application. On the contrary, such knowledge should be considered part of a global common because of its nature as open knowledge available to everyone and because of its location in common areas where no one can assert property rights or “sovereign rights” within the meaning of section 2 of this chapter. By the same token, application, by analogy, of the regime of freedom governing marine scientific research also does not lead to the conclusion that such freedom entails the right to appropriate the bio-genetic resources of common spaces. On the contrary, rules relating to marine scientific research are activity-related, in the sense of establishing rights and obligations applicable to the conduct of science operations at sea. But in no way can such rules, customary or contained in Part XIII of the LOS Convention, be used to establish ownership or sovereign rights over resources. This is made clear by Article 241 of the LOS Convention, which provides that:

“Marine scientific research activities shall not constitute the legal basis for any claim to any part of the marine environment or its resources”.

Seen against this background, the issue of which regulatory model should govern access and exploitation of genetic resources located in common spaces cannot be laid to rest with either the “sovereign rights” model or the free for all regime. The correct solution, therefore, must be found in a public common regime, based on the recognition that genetic material found in such spaces constitutes the common estate of humanity, for the conservation and exploitation of which international mechanisms are needed, ensuring co-operation and institutional oversight. No such specific mechanism exists today. However, if we were to follow a simple criterion of competence *ratione loci*, it would be logical to identify the competent institution for marine genetic resources as the International Sea Bed Authority. The mandate of this body is, it must be granted, limited to the management of mineral resources in the international seabed area. However, nothing would prevent the states party to the LOS Convention from formally extending jurisdiction to this new type of resource, unforeseen at the time of the UNCLOS negotiations. In the alternative, an “evolutive” interpretation of Part XI of the Convention could be adopted, taking into account the criterion of “proximity” of the most important genetic resources to the hydrothermal vents in the deep seabed area.<sup>47</sup> Or, this issue might be considered in the context of on-going initiatives for UN

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<sup>46</sup> Pisillo Mazzeschi, 1978

<sup>47</sup> For an assessment of the potential in the genetic traits of organisms living in extreme environmental conditions, with scarcity of light and temperature variations, see Scovazzi, *cit.*, note 44.

system reform with a view to establishing a new International Environmental Organization,<sup>48</sup> whose mandate would also include standard-setting and the monitoring of prospecting and exploitation activities aimed at genetic resources in the seas beyond national jurisdiction.

However, entrusting the implementation of common heritage to an existing international institution, or to one to be constituted *ad hoc*, is not the only solution. The principle of common heritage in its substantive aspect is, like any norm of international law, perfectly capable of being applied in a decentralized manner by states. Even in the absence of *ad hoc* institutions every state is under an obligation to respect and fulfil the principle of the common heritage by ensuring that subjects within its jurisdiction do not act contrary to its object and purpose. This would be the case if a state authorized or negligently failed to prevent biotechnological activities in common spaces that had the effect of causing severe and irreversible damage to the unique biodiversity of that space. Similarly, a State would fail the common heritage if it authorized exclusive appropriation of genetic resources without requiring equitable sharing of pertinent scientific knowledge and without ensuring that a fair portion of economic benefits accruing from their exploitation be devoted to the conservation and sustainable development of such common resources.<sup>49</sup> Similar criteria apply to the genetic resources of Antarctica. Here, the forty plus years of uninterrupted co-operation within the framework of the Antarctic Treaty (1959)<sup>50</sup> would give the Antarctic Treaty Consultative Meeting (ATCM) undisputed authority to regulate bio-prospecting in the Antarctic Treaty Area, in the interest of humankind and in conformity with the principle of free exchange of scientific information.<sup>51</sup>

The criteria above do not entail that the international seabed or Antarctica may not be treated like great laboratories open also to private scientific operators interested in the biotechnological development of the respective resources. On the contrary, it simply entails that a) access to these resources occur within a regulatory framework capable of preserving the interest of humankind in the conservation and sustainable development of these areas; b) the technological advances and financial return produced by bio-prospecting be equitably shared, under the authority of relevant international institutions or multilateral regimes such as the International Sea Bed Authority or the ATCM; and c) in the absence of multilateral mechanisms, individual states regulate bio-prospecting and exploitation of the genetic resources of common spaces with full respect for their character as part of the common good of humanity, so as to avoid recognition of ownership and appropriation simply on the basis of earlier finding and discovery.<sup>52</sup>

#### 4. Individual and Collective Human Rights

Having clarified the manner in which international law allocates rights of control over bio-genetic resources, we can now proceed to the examination of the way in which

<sup>48</sup> See F. Francioni, "The Role of the EU in Promoting Reform of the UN in the Field of Human Rights and Environmental Protection", in *The European Union and the United Nations*, Institute for Security Studies, Paris, 2005, p. 31 ff. .

<sup>49</sup> See B. Conforti, "Notes on the Unilateral Exploitation of the Deep Seabed", 4 *IYIL*, 1980, p. 3 ff..

<sup>50</sup> See <<http://sedac.ciesin.org/entri/texts/acrc/at.txt.html>>

<sup>51</sup> See Francioni, "Antarctica and the Common Heritage of Mankind", Milano, in *International law for Antarctica*, (Francioni and Scovazzi Eds.) Milano 1987. p, 101 ff.

<sup>52</sup> For a precedent applying these criteria in the domestic law context, see *Edmonds Institute, et al. v. Bruce Babbit* (U.S. District Court for the District of Columbia, 24 March 1999, available at <<http://www.edmonds-institute.org/yellowstone98561.pdf>>), concerning Yellowstone National Park.

biotechnology applied to such resources affects internationally recognized human rights. The scope of this part of the chapter is limited to a general overview of human rights guaranteed under general international law. Other contributions in this volume will address human rights issues arising from the regulation of biotechnology in specific treaty regimes and in international organizations.<sup>53</sup> In this perspective, one must recognize at the outset that the content and scope of the category of international human rights under customary international law remains somewhat elusive. Faced with a vast array of treaty and soft-law instruments on the protection of an infinite variety of human rights, what the universally shared core of human rights states must respect and protect as a matter of customary international law continues to be the object of debate. Globalization, with its powerful integrative force at the economic, social and cultural level, has the effect of raising levels of rights awareness in the most diverse legal systems, thus fostering recognition of basic human rights as the mainstay of an open and democratic society. At the same time, for the recurrent law of “unintended consequences”, the historical process of globalization is also fuelling a centrifugal trend toward the search for specific identity, often found in opposition to cosmopolitan values in the traditions and moral beliefs of the nation, of minorities or groups. This phenomenon is particularly evident in the area of “cultural rights”, where claims to the enactment and respect of a specific world view and practice may be pitted against internationally recognized human rights and even the rights of individuals within the group. Such antinomy between the universal and the particular complicates, but does not exclude, the identification of a core of generally recognized human rights rooted in the inherent value of human dignity and shared humanity. The International Court of Justice,<sup>54</sup> the practice of international criminal tribunals<sup>55</sup> and State practice, including that of national courts,<sup>56</sup> recognize the existence of a body of customary international law on human rights binding upon states independent of their consent to specific treaties. This body of law has been constantly expanding since the adoption of the UN Charter and of the Universal Declaration of Human Rights. It includes today the prohibition of the most egregious violations of human dignity, such as genocide, slavery, torture and racial discrimination, as well as of violent suppression of the right to self-determination of peoples, of prolonged and widespread deprivation of personal liberty and of so-called “gross violations of human rights”.<sup>57</sup> The emergence of these rights has contributed to the transformation and modernization of international law from a legal order governing diplomatic relations between states to a more mature legal order applicable also to non-governmental actors. The implications of this transformative process are far-reaching. First, states can be held internationally accountable also toward individuals at the level of primary human rights obligations, even if secondary rules on responsibility and remedies may still be lacking or limited to regional human rights regimes, notably the European Convention and the Inter-American System. Second, human rights obligations are not reciprocal, like most classic customary international law obligations, but are integral, owed to the international

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<sup>53</sup> See chapters by S. Millns, E. Righini, A. Yusuf, Abbot, Mechlem and Rainey, Petersmann, Galligan. In this volume....

<sup>54</sup> See *Barcelona Traction, Light and Power Company, Limited (Belgium v. Spain)*, 1970; *Military and Paramilitary Activities in and Against Nicaragua (Nicaragua v. United States of America)*, 1991; Advisory Opinion on the *Legality of the Threat or Use of Nuclear Weapons*, 1996; Advisory Opinion on the *Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory*, 2004, all these judgements are available at <<http://www.icj-cij.org/idecisions.htm>>

<sup>55</sup> See Cassese *International Law*, Oxford, 2003, p.393 ff.

<sup>56</sup> For a comparative overview of national courts' treatment of international human rights obligations, see B. Conforti and F. Francioni (eds.), *Enforcing International Human Rights in Domestic Courts*, The Hague/Boston/London, 1997.

<sup>57</sup> ALI, Restatement, 1987



community as a whole; thus, they operate *erga omnes*.<sup>58</sup> Third, the assumption that every State has an interest in the respect of basic human rights as a matter of international public policy has contributed to the “constitutionalization” of a core of fundamental human rights norms in terms of *jus cogens*, or peremptory norms, endowed with inherent normative strength so that no single state, alone or in conjunction with others, may dispose of them at will. In this perspective, *jus cogens* represents the most powerful legal tool to support the concept of “international community”, as a collective entity that transcends the sovereignty of states and encompasses them *uti universi*. Fourth, the idea that fundamental human rights constitute a common concern of the international community has led to the development and enforcement of the principle of international criminal liability of individuals who commit serious violations of human rights falling within the category of international crimes.<sup>59</sup>

The considerations above are especially relevant in the context of a discussion on the role of human rights in the international regulation of biotechnology. First of all, they indicate that, even though the status of and access to genetic resources may still be subject to “sovereign rights”, the legitimacy of their biotechnological applications must be gauged in accordance with human rights standards, in respect of which the international community as a whole has a legal interest. Secondly, the very notion of international human rights entails that relative standards are binding not only upon states, whose sovereignty is thereby limited, but, at least in an indirect manner, also on private actors, especially powerful new scientific and economic entities – science concerns and business corporations – which can command the technological power necessary to develop and market genetically engineered products. Finally, the introduction of human rights discourse into biotechnology regulation will necessarily entail a deconstruction of the unity and indivisibility of the sovereign state to identify whose individual or collective human rights are actually affected by biotechnology applications.

In the remaining part of this chapter I will look through the lens of this complex normative development to try to discern which human rights are most directly affected by biotechnologies. The focus will be on the following set of rights: 1) human dignity, 2) non-discrimination, 3) self-determination, 4) rights pertaining to the human body, such as life, integrity, health, 5) economic and social rights, including intellectual property rights and sustainable development. This is by no means an exhaustive catalogue of human rights potentially affected by bio-engineering techniques. But it represents the preliminary legal framework within which a more detailed analysis of the human rights involved in biotechnology applications can be developed. This will be the task of the specific contributions in this volume which are devoted to particular regulatory regimes and to specific categories of human rights.<sup>60</sup>

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<sup>58</sup> See *Barcelona Traction, Light and Power Company, Limited (Belgium v. Spain)*, 1970 and *Advisory Opinion on the Wall, cit.*, note 54; Simma. *Academy of European Law*, collected courses, 1995

<sup>59</sup> This happened, in particular, with the institution of the International Criminal Tribunal for the Former Yugoslavia (ICTY) in 1993 (the text of the Statute is available at <<http://www.un.org/icty/legaldoc/index.htm>>), of the International criminal tribunal of Rwanda (ICTR) in 1994 (the text of the Statute is available at <<http://www.ict.rw/ENGLISH/basicdocs/statute/2004.pdf>>), and of the International Criminal Court (ICC) in 1998 (the text of the Statute is available at <<http://www.un.org/law/icc/statute/rome fra.htm>>)

<sup>60</sup> See Part II, III, IV, V and VI of this volume.

## 5. Human Dignity.

The broadest human right concept invoked in the context of biotechnology is human dignity. This is a fundamental concept in international human rights law. The 1948 Universal Declaration refers to it in the Preamble as "... the foundation of freedom, justice and peace in the world"<sup>61</sup> and incorporates it in Article 1, which states that "... human beings are born free and equal in dignity and rights". Subsequent human rights instruments have systematically referred to human dignity as the foundation and wellspring of specific human rights.<sup>62</sup> In Europe, the value of human dignity constitutes the cornerstone of the 2000 Charter of Fundamental Rights (Article 1), now incorporated in the Treaty adopting a Constitution for Europe (Article II-61).<sup>63</sup> In the well known case *Netherlands v. European Parliament and Council*, Advocate General Jacobs stated that human dignity is "...perhaps the most fundamental right of all, and is now expressed in Article 1 of the Charter".<sup>64</sup> In the field of biotechnology the concept of human dignity works as a threshold standard against which to test the different applications of genetic engineering techniques. In this role it performs a dual function: 1) on the one hand, it may provide the ethical and legal justification for the development and application of new biotechnologies; and, 2) on the other, it is the guiding principle in setting boundaries to the permissibility of the variety of policy options offered by biotechnologies in fields such as bio-medicine and agriculture.

1) As an ethical justification for the development and application of new biotechnologies, human dignity can play an important role in supporting the legitimacy of cutting edge scientific research in the field of medicine and genetic therapy for hereditary or otherwise incurable diseases, and generally in promoting participation in scientific progress consistent with Article 27 para. 1 of the Universal Declaration of Human Rights.<sup>65</sup> The potential benefits of such progress, especially for people who suffer, or may be born suffering, from severe diseases and disabilities of a genetic nature constitute a powerful ethical and human rights argument to counter-balance the cultural or religious objections of those who are opposed to playing with a matter of life or the design of nature.<sup>66</sup> Similarly, in the field of agriculture, respect and protection of human dignity can be an important factor in adopting a policy favourable to the introduction of genetically modified crops or the distribution of genetically modified food when this represents the most effective way to deal with situations

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<sup>61</sup> See the first recital, which reads as follows: "[w]hereas recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world". Human dignity is also referred to in the fifth recital, which states: "[w]hereas the peoples of the United Nations have in the Charter reaffirmed their faith in fundamental human rights, in the dignity and worth of the human person and in the equal rights of men and women and have determined to promote social progress and better standards of life in larger freedom".

<sup>62</sup> See, for instance, the preamble to the *Supplementary Convention on the Abolition of Slavery, the Slave Trade, and Institutions and Practices Similar to Slavery* (1956), *UNTS*, Vol. 266, p. 3; the Preamble of the *International Convention on the Elimination of All Forms of Racial Discrimination* (1966), *UNTS*, Vol. 660, p. 195; the Preamble of the two 1966 UN covenants on human rights (see *International Covenant on Economic, Social and Cultural Rights*, *UNTS*, vol. 993, p. 3; *International Covenant on Civil and Political Rights*, *UNTS*, vol. 999, p. 171); the Preamble of the 1973 *International Convention on the Suppression and Punishment of the Crime of Apartheid*, available at <<http://www.unhchr.ch/html/menu3/b/11.htm>>; the preamble of the 1984 *Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment*, 24 ILM, 535 (1985).

<sup>63</sup> Further on human dignity and common values in Europe, see S. Millns, in this volume.

<sup>64</sup> Opinion of Advocate General Jacobs of 14 June 2001 in the case C-377/98, (2001) ECR I-7079, para. 197.

<sup>65</sup> See *supra*, note 6.

<sup>66</sup> Campiglio, Human Genetics, Reproductive Technology and Fundamental Rights, XIV Italian Yearbook Int. L.,(2005), p. 83 ff.

of severe poverty, famine or malnutrition that endanger the dignity, subsistence and the very life of people.<sup>67</sup>

2) As a constraint, human dignity has already begun to perform a specific role in relation to the manifold applications of biotechnologies, notably in the field of biology and medicine. The UNESCO UDHG, with related instruments, the Council of Europe Biomedicine Convention, as well as the Charter of Fundamental Rights included in the Constitution for Europe, are all based upon the primacy of human dignity over the interests of scientific research and technological innovation. In particular, respect for human dignity entails that biotechnological applications in the field of medicine shall: 1) respect the uniqueness and diversity of human beings and, accordingly, avoid a reduction of individuals to their genetic characteristics;<sup>68</sup> 2) respect the free and informed consent of interested persons, in accordance with the modalities established by law; 3) avoid eugenic practices, especially those aimed at the selection of human beings; 4) be based upon the principle that the human genome and parts of the human body may not be disposed of for monetary gain; and, 5) shall conform to the basic prohibition of reproductive human cloning.<sup>69</sup> Of course, recourse to such a fluid and open-ended concept as human dignity leaves undecided what is “human” and whether technological application on the stem cells of human embryos is permissible in view of therapeutic benefits, as discussed above. This remains a contentious area, where national legislation and, more importantly, fundamental ethical standards in different societies continue to diverge. In particular, there is no consensus on the question of when human life begins,<sup>70</sup> whether human embryos are protected under the principle of human dignity, whose consent is relevant – the parents?, the spouse?, the future human being?, the beneficiary? – and, ultimately, on how to balance protection of the nascent life of the embryo with other legitimate objectives, such as protection of the health of others, the self-determination of the mother, the rights of the spouse or the utilization of the embryo cells for scientific and therapeutic purposes. Given the highly subjective concept of “human dignity” and differing ethical perceptions of the stage of life formation at which the term “human” and the empowering notion of “dignity” may apply, it is impossible, at least in the short term, that a human right approach may develop solely on the basis of a universally shared notion of human dignity. This, however, does not mean that the concept is useless. In my view, it provides an important legal tool to establish a dialogue between different and sometimes radically opposed ethical camps. It permits a better understanding of the interests and reasons involved in the moral claims of others, whether to absolute respect for the sacrality of life or to the need of making use of the opportunities science offers to prevent or remedy severe genetic diseases capable of impairing or destroying the dignity of the bearers.

## 6. Non-Discrimination

One of the positive consequences, in moral and social terms, of genetic science, and in particular of the Human Genome Diversity Project (HGDP), is the production of scientific evidence that there is no biological basis for the concept of “race” and that persons belonging

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<sup>67</sup> Mechlem and Raney, in this volume.

<sup>68</sup> See Article 2 of the Universal Declaration on the Human Genome and Human Rights, *supra*, note 14. On this point, see N. Lenoir, “La Déclaration Universelle sur le génome humain et les droits de l’homme de l’UNESCO”, in *Rapport public du Conseil d’Etat*, 1998.

<sup>69</sup> See Article II-63 of the 2004 *Treaty establishing a Constitution for Europe*.

<sup>70</sup> See the case of *Vov. France*, decided by the European Court of Human Rights, 8 July 2004, \_\_\_\_\_

to the same racial-ethnic group may indeed have a more diverse genetic patrimony than people who may be profiled as belonging to different racial groups. This disclosure of the “universality” of the human genome is, no doubt, a significant contribution to the consolidation of the ethical basis of the principle of non-discrimination. This has been acknowledged by the UDHR, which states that the human genome “underlies the fundamental unity of the human family” (WHERE DOES IT STATE THIS?): This principle provides also the rational justification for the inclusion of a non-discrimination norm in virtually all human rights treaties.<sup>71</sup>

At the same time, genetic science and technology, especially in the field of medicine, are raising new possibilities of discrimination. From a general point of view, the most threatening type of discrimination can come from a new conceptualization of “normality” based, rather than on the natural definition as a state of physical and mental well being, on a genetic connotation, which includes the hidden predisposition to some health impairment or, conversely, the search for a certain quality of life. In this context, it is clear that the more genetic tests and therapies are made available, the greater the gap will grow between the fortunate who have access to such tests and therapies and those who do not. This new “discrimination” would run along the fault line that separates the rich world from the less developed world.<sup>72</sup>

At a more practical level, the principle of non-discrimination may play an important role in genetic patenting. A recent case brought before the European Patent Office offers an example of race utilization in patent specification. Myriad Genetic claimed a patent relating to a gene probe “for diagnosing a predisposition to breast cancer in Ashkenazi Jewish women”. The relevant gene mutation related to ovarian and breast cancer and was found to be prevalent in Ashkenazi Jewish population in the order of 1% as compared to 0.1% of the general population. The European Society of Human Genetics strongly opposed diagnostic targeting of a racial group in a gene patent application. In particular, it argued that genetically discriminating considerations are contrary to *ordre public* and public morality. The European Patent Office decided to up-hold the patent in amended form, stating that it “relates to use of a particular nucleic acid carrying a mutation of the BRCA 2-gene, which is associated with a predisposition to breast cancer for in vitro diagnostic of such predisposition in Ashkenazi Jewish women”.<sup>73</sup>

But the area where the risk of discrimination on a genetic basis is the highest and most disturbing is that of insurance and employment. Here the questions arise: 1) whether insurers and employers may be allowed to require genetic tests as a condition of insurance or employment; 2) whether insurers or employers may require disclosure of prior genetic tests by the applicant; and 3) whether insurers or employers may give weight for business purposes to genetic information voluntarily provided by applicants. *Prima facie*, the answer to these questions appears to be negative in the light of the norms contained in universal and regional instruments on bioethics. For example, Article 11 of the Council of Europe Convention on Biomedicine stipulates that “any form of discrimination against a person on grounds of his or her genetic heritage is prohibited”. More specifically, Article 12 prohibits predictive tests except for health or scientific research reasons. The same principles are upheld in the UDHR

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<sup>71</sup> See for example, Article 14 of the European Convention on Human Rights with additional Protocol N. 12, Article 1 paragraph 1 of the American Convention, Articles 2, 14 and 26 of the International Covenant on Civil and Political Rights.

<sup>72</sup> For an in depth analysis of these implications, see the yet unpublished PhD thesis by A. Rouvroy, *Human Genetic and Justice: Sustaining Uncertainty*, European University Institute, Florence, 2005

<sup>73</sup> EPO press release, Patent on Breast Cancer Gene-2 maintained in amended form after public hearing, 29 June 2005..

(Article 6), in the International Declaration on Human Genetic Data (Articles 7 and 14). And in the ECOSOC Resolution on Genetic Privacy and Non-Discrimination, of 22 July 2003, which urges States “to ensure that that no one shall be subjected to discrimination based on genetic information; also urges States to protect the privacy of those subject to genetic testing and to ensure that genetic testing and the subsequent processing, use and storage of human genetic data is done with the prior, free, informed and express consent of the individual or authorization obtained in the manner prescribed by law consistent with international law, including international human rights”. (THERE IS NO CITATION) As we can see the international standards on non discrimination are clear. Therefore genotypic differentiations resulting in a discriminatory treatment in the field of employment and insurance are not permissible. Naturally, to translate these standards into enforceable prohibitions in domestic law requires precise regulation and a considerable degree of public intervention in insurance and employment markets where private lobbies may show considerable resistance. However, it is fair to say that so far, even in those countries where health care is provided by private insurance, there is no indication that genetic science may be leading to systematic discrimination and to the creation of a “genetic underclass”<sup>74</sup> of unemployable and uninsurable people.

## 7. Self-determination.

Self-determination, originally conceived as the right of peoples to accede to self-government, has become an important component of international human rights. The two UN Covenants, on Civil and Political Rights,<sup>75</sup> and on Economic, Social and Cultural Rights,<sup>76</sup> are both premised on recognition, in identical terms, of the right to self-determination in their respective Article 1. Similar recognition can be found in the 1982 African Charter of Human and Peoples Rights.<sup>77</sup> At the core of this right is the entitlement of all peoples to “... freely determine their political status and freely pursue their economic, social and cultural development”.<sup>78</sup> But how can this rather indeterminate right be relevant to the governance of biotechnology in the post-colonial world?

First, as indicated in section 2 of this chapter, self determination complements and reinforces the sovereign right of all peoples to “freely dispose of their natural wealth and resources”<sup>79</sup> including biogenetic resources within their territorial jurisdiction. As a collective right of the “peoples”, self-determination also entails the right to freely pursue economic, social and cultural development.<sup>80</sup>

Second, in its external dimension, this right also entails that States, especially developing States, are entitled to pursue economic policies aimed at protecting their population against the damaging impacts and unwanted risks of biotechnology applications. This is all the more true given that the spread of biotechnology and of its products, especially in the field of agriculture, depends on the business practices of a relatively small number of

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<sup>74</sup> This expression is used by Rouvroy, *op. cit.*, *supra* note 72, at 139.

<sup>75</sup> See *supra*, note 62.

<sup>76</sup> *Ibid.*

<sup>77</sup> See Article 20.

<sup>78</sup> See Article 1, para. 1 of the two UN Covenants on human rights (*supra*, note 62).

<sup>79</sup> See Article 1 para. 2 of the *International Covenant on Civil and Political Rights*, *supra*, note 62.

<sup>80</sup> For a recent reaffirmation of this right, see the ICJ advisory opinion on the *Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory*, 9 July 2004, *supra*, note 54.

corporations, all based in the advanced industrial world and increasingly characterized by a high degree of vertical integration.<sup>81</sup> These corporations have an important role as vectors of scientific progress and economic development. Their inventions and know-how can enhance agricultural productivity, provide more nutritious food<sup>82</sup> or new pharmaceutical products, and generally improve the welfare of people. But, at the same time, one cannot ignore that these companies all belong to the private sector and are commercially driven toward the development of biotech products and services capable of ensuring satisfactory financial returns for their conspicuous investments.<sup>83</sup> Besides, they operate in a markedly asymmetrical relationship with developing countries. They rely on structurally superior knowledge of the technological processes and products they market, and consequently on superior knowledge of risks. They enjoy the bargaining advantage of disposing of large finance capital for investment, for which less-developed countries desperately compete. And, most importantly, they claim that, at least in a strict legal sense, they are not “subjects” of international law, so as to be able “legally” to elude international human rights standards binding upon states.<sup>84</sup> This may lead to abuses and unfair market practices in their relations with host countries in the planning and conduct of foreign operations. While this is a general problem arising in relation to the activities of all trans-national corporations, the impact on a sphere of interest protected by the principle of self-determination can be more substantial in the case of bio-tech companies. New and untested biotechnology experimentation on plants or animals may take place in a foreign country without the prior informed consent of local authorities and people, taking advantage of a lack of legislative regulation or infrastructure, or inadequate administrative control.<sup>85</sup> Aggressive marketing strategies aimed at introducing new biotech products, such as genetically modified seeds that farmers are not allowed to reuse, may cause dependence on foreign supply and consequent indebtedness, while at the same time disrupting long established and socially sound patterns of farming techniques.

All states, especially less-developed states, are entitled to invoke the right of self-determination of (their) peoples to protect societal values and sustainable economic structures from the adverse impact of unethical or unfair business practices on the part of international biotech corporations. This, of course, may raise problems with obligations of free trade and market access within the WTO, especially now when so many developing countries are, or

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<sup>81</sup> Following a process of mergers and consolidation there are now five large companies dominating the biotech market in the area of food and agriculture. See Mechlen and Raney, in this volume

<sup>82</sup> As in the case of so-called “golden rice”, a biotech rice enriched with vitamin A, capable of providing a low cost alternative to a more diversified but often unaffordable diet in many poor countries of the world where rice represents a main staple.

<sup>83</sup> The top ten multinational biotech corporations account for US \$ 3 billion per year only for agricultural biotechnology research and development. In contrast the total FAO budget for research in crop improvement within the Consultative Group on International Agricultural Research amounts to US \$ 300 million. See Mechlem and Rainey, in this volume, and FAO, *The State of the Food and Agriculture 2003-04 – Agricultural Biotechnology: Meeting the Needs of the Poor?*, Rome, FAO publications, 2004, p. 32 ff.

<sup>84</sup> We cannot undertake a discussion of the question whether business corporations, as international “actors”, may *de facto* be subject to international human rights or environmental standards here. The concept of “actorship” in international law is still undefined and is often used in a less than rigorous manner to mean international law as “global” law, transcending the traditional distinction between the domestic and international legal order. It is worth mentioning, however, that a step toward the recognition of corporations as economic entities capable of being accountable under international human rights standards has been made by the UN Sub-Commission on the Protection and Promotion of Human Rights with the adoption in 2003 of a set of “norms on the responsibility of transnational corporations and other business enterprises with regard to human rights”. See UN Doc. E/CN.4/Sub.2/2003/12/Rev.2 of 26 August 2003.

<sup>85</sup> See the T. McGarity, *International Regulation of Deliberate Release Biotechnologies*, in *International Responsibility for Environmental harm*, (Francioni and Scovazzi Eds.), London, 1991, p. 319 ff.

are becoming, members of the Organization. However, this problem cannot be addressed by advocating an inflexible application of free trade principles. On the contrary, as other contributions in this volume will discuss,<sup>86</sup> it requires a human rights approach to trade, based on a broad construction of every state's freedom and responsibility to set an appropriate level of protection for its fundamental societal values, of which the principle of self-determination constitutes the essential core.

A third way in which self-determination can play a role in developing a human rights approach to the legality of modern biotechnology is in relation to the special protection of distinct minorities, groups or peoples whose genetic characteristics or special environmental resources are targeted by bio-science research and industry in view of the development of new products and commercial applications. In this "internal" dimension, the principle of self-determination guarantees a certain degree of autonomy to the peoples concerned, within the constitutional structures of existing States. This entails the obligation, from the point of view of collective human rights, for every state to take into account the interests of such distinct groups, and especially of indigenous peoples, in maintaining and managing their distinct culture and special and sometimes unique relationship with their land and its biological resources. This particular dimension of the right to self-determination entails a limitation on the sovereign rights of the territorial State, both in the sense that a) biotechnological projects involving indigenous peoples, or other distinct groups, should be based on the effective participation of these peoples in decisions that affect them and their environment;<sup>87</sup> and that b) eventual economic benefits accruing from indigenous peoples' genetic patrimony, from the biological resources of their environment and from the traditional knowledge that has permitted conservation and development should be equitably shared with such peoples.<sup>88</sup>

## 8. The Human Body.

These last remarks introduce us to the most sensitive aspect of biotechnology applications: the bio-prospecting and engineering of parts of the human body in the expectation of finding useful genetic material for diagnostics and therapy for certain inherited diseases. Research has been booming in this field for a number of years; and experience already shows that, while advances in gene therapy may hold the promise of improving the life and health of people, a number of potential adverse impacts on human rights may result. A particularly telling example is that of the experimental use of cell lines – with a living cell proliferating, under appropriate laboratory conditions, into multiple cells that will form a durable cell line – to be studied and manipulated for possible medical applications. An early

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<sup>86</sup> Petersmann, *Biotechnology, Human Rights and Trade*, in this volume

<sup>87</sup> For an important application of this principle, see Human Rights Committee, General Comment No 23 of 6 April 1994 on Article 27 of the Covenant on Civil and Political Rights (available at <<http://www.ohchr.ch/english/bodies/hrc/comments.htm>>), and the decision of the Inter-American Court of Human Rights of 31 August 2001 in the case *Awas Tingni Mayagna (Sumo) Indigenous Community v. Nicaragua* (Communication No. 167/1984, 26 March 1990, available at <<http://www.unige.ch/humanrts/undocs/session45/167-1984.htm>>) recognizing that the collective right of indigenous people to their ancestral land and resources prevailed over the Government's sovereign power to dispose of them by way of licensing their exploitation to foreign investors. Further on this case and on the general question of the biogenetic resources of indigenous peoples, see Lenzerini, in this volume.

<sup>88</sup> See Article 8 (j) of the Convention on Biological Diversity (*supra*, note 1), which, however, uses the word "encourage" with regard to the sharing of benefits deriving from the utilization of traditional knowledge and practices relating to biological resources.

experiment on cell lines at the end of the 1980s involved the taking of human tissues from a small and fairly remote tribe of indigenous people from Papua New Guinea in order to study their “unique” characteristics and their possible application in the early detection and eventual cure of adult leukaemia and other degenerative disorders.<sup>89</sup> This and similar initiatives, which were part of the well-known HGDP,<sup>90</sup> were undertaken in the exercise of unfettered freedom of scientific research, in the absence of genuine capacity on the part of the tribe to provide prior and informed consent, and on the questionable assumption that the peoples whose body provided the valuable tissue samples were mere “objects”, rather than persons endowed with inherent human rights. No wonder, then, that such precedents have spurred a widespread movement among indigenous populations, especially in Latin America and Asia, in opposition to the HGDP, suspected of opening the door to abuse of human genetic material for commercial and even military purposes.<sup>91</sup> To avoid such *a priori* opposition to genetic research a more cautious approach, taking into account respect for human dignity, a right to personal integrity, and the individual and collective right to maintain control over genetic heritage and to decide whether to make (their) DNA available for scientific experimentation, is necessary. This approach has been followed by UNESCO since the adoption of the 1997 UDHG,<sup>92</sup> the first truly universal instrument<sup>93</sup> to set ethical standards on human genetic research and practice. The Declaration carefully balances freedom of scientific research against the need to safeguard human rights and the general interest of humanity against possible abuses. Besides proclaiming the human genome “the heritage of humanity”,<sup>94</sup> the declaration establishes, in Article 5, that research, treatment or diagnosis affecting a person’s genome must be undertaken only on the basis of “... the prior, free and informed consent of the person concerned”. More important, the same article provides that when “... a person does not have the capacity to consent, research affecting his or her genome may be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law”.<sup>95</sup> This formulation leaves ample margin of appreciation for national law-makers to decide when and under what specific conditions research and technological applications affecting someone’s genome are permissible. But, as in the case of human dignity, reference to the paramount importance of a direct health benefit to the individual permits bridging the gap between different ethical views, leading to possible convergence in a shared ethical conception of the human person as an end in herself (and not a means to achieve technical or economic goals).

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<sup>89</sup> For a full account of this case see J. Rifkin, *The Biotech Century: Harnessing the Gene and Remaking the World*, New York, 1998, p. 50 ff.

<sup>90</sup> The HGDP is a consortium of Scientists from North America and Europe aimed at collecting live tissues from hundreds of different human groups throughout the world in order to map the human genome. See “The Human Genome Diversity project”, *GenEthics News*, issue 10, available at <<http://www.hgalert.org/topics/personalInfo/hgdp.htm>>

<sup>91</sup> Further on this problem see F. Lenzerini, “Biogenetic Resources and Indigenous Peoples’ Rights”, in this volume.

<sup>92</sup> See *supra*, note 14.

<sup>93</sup> The Convention on Human Rights and Biomedicine (see *supra*, note 19) is a regional instrument that remains of limited geographic scope and application.

<sup>94</sup> See article 1.

<sup>95</sup> This provision appears to be particularly important to meet the concerns of indigenous people. See the chilling statement by Victoria Tauli-Corpuz, representative of the Cordillera People’s Alliance, Philippines: “After being subjected to ethnocide and genocide for 500 years, which is why we are endangered, the alternative is for our DNA to be stored and collected ... Why don’t they address the causes of our being endangered, instead of spending \$ 20 million for five years to collect and store us in cold laboratories.” (cited by Lenzerini, *cit.*, note 86, p. 6).



## 9. Economic Rights and Benefits.

Economic rights and benefit-sharing in relation to modern biotechnologies are “transversal” issues arising from all biotechnology applications in fields as diverse as human genetics, plant genetic resources, pharmacy, agriculture and industry. Given the growing importance of biotech business in these different fields, it is no wonder that the ethical question of who is to benefit from the commercial application of such science has been cast increasingly in human rights terms. The High Commissioner for Human Rights’ Expert Group on Human Rights and Biotechnology has focused especially on the problematic relationship between genetic patenting and equitable sharing of the economic benefits accruing from commercial exploitation of the patented material. In its 2002 report, the Group goes as far as to consider “the linked issues of the ability to patent genetic material and the sharing of benefits deriving from commercial exploitation of that material to be the most important issue in the area of human rights and biotechnology at this time”.<sup>96</sup> From a human rights perspective this issue requires that we determine what the conditions and limits of property rights over genetic material are, on the one hand, and what the legal basis for recognizing the economic rights of individuals or groups from whose body or natural environment the material has been extracted may be, on the other. This preliminary determination is by-passed by those commentators who are satisfied with the reference to a generic principle of “equitable benefit sharing”, sometimes even considered a veritable rule of customary international law.<sup>97</sup> Although reference to equity in this field is welcome and can indeed be useful, inasmuch as it opens the way toward pragmatic accommodation of differing competing interests, it can be only of limited use in a human rights approach to the problem. The latter approach posits a use of equity *infra legem* and not in a legal vacuum. Thus, it requires the prior identification of the legal entitlements that are at stake under international and human rights law. And permits the equitable balancing of conflicting legal interests by appropriate techniques of interpretation and implementation of international norms. In this perspective, “equitable benefit-sharing” is the problem to be addressed, rather than the normative tool providing a key to any solution. Benefit-sharing cannot be “de-contextualized” from the individual and collective rights that form its basis. As I have tried to indicate in the first part of this chapter, the identification of relevant titles and rights – peoples’, humanity’s, community’s, individuals’ – is a pre-requisite for the determination of legal conditions of access to genetic resources and to the sharing of economic benefits among relevant stakeholders. In this context, “equity” is a variable element whose function is to infuse considerations of justice and fairness into the balancing of competing rights. Variation depends on the type, location and origin of the relevant genetic stock.

In relation to plant and animal genetic resources found in the territory of states, the function of equity is quite clear: since present international law<sup>98</sup> recognizes the territorial state’s sovereign rights over such resources, equity has the function of striking a fair balance between, on the one hand, the claim of the investor to protect biotechnological inventions, including property rights arising therefrom, and, on the other, the sovereign right of the source state to obtain equitable remuneration for the exploitation of its biodiversity, including

<sup>96</sup> See High Commissioner’s Expert Group on Human Rights and Biotechnology, “Conclusions”, Geneva, 24-25 January 2002, available at <<http://www.unhchr.ch/biotech/conclusions.htm>>, par. 19.

<sup>97</sup> See R. Pavoni, *Biodiversità e biotecnologie nel diritto internazionale e comunitario*, Milano, 2004, esp. Chapt. III and IV.

<sup>98</sup> See, in particular, the Biodiversity Convention (*supra*, note 1) and the FAO Treaty on Plant Genetic Resources (*supra*, note 9).

remuneration for local communities' traditional knowledge, which permitted or facilitated the identification and utilization of the relevant genetic material in the first place.

By contrast, in the context of biotechnological development of genetic resources originating in common spaces beyond national jurisdiction – such as the international sea and seabed, and Antarctica – the role of equity is totally different. Here, equity is called on to accommodate the claim to exclusive property rights of the biotech investor and the general interest of humanity in the identification, conservation and sustainable development of such resources pursuant to common heritage or common concern principles. This entails that the grant of patents over biotechnological applications to such common resources, besides respecting the usual conditions of patentability – novelty, inventive step, capability of industrial application – must be compatible with the global common nature of these resources and the public interest of humanity in maintaining knowledge and control over their development. In this context, the practical requirements to achieve such compatibility ought to include: 1) the duty of the patent applicant to disclose the provenance of the genetic material;<sup>99</sup> 2) the possibility of invalidation of the patent in the event of intentional misrepresentation of the origin of genetic resources; 3) effective use of the patent to support scientific progress, rather than simply produce genetic enclosure with the effect of blocking the development of knowledge and innovation (as in the case of dormant patents)<sup>100</sup>; 4) peaceful use of the genetic resources; and, 5) the equitable sharing of benefits in the form of international pooling of knowledge and, if practicable, by payment of reasonable royalty-fees to recognized international institutions competent in the management and conservation of the relevant common resource.<sup>101</sup>

Finally, in relation to human genetic resources, the concept of equitable sharing of economic benefit must take into account the proclaimed nature of the human genome as “common heritage of humanity”<sup>102</sup> – with its corollary that the human genome in its natural state shall not give rise to financial gains<sup>103</sup> – and the competing claims of researchers, biobanks and other biotech investors to proprietary rights in the genetic material and in given biotech inventions. The state of play today reveals that overwhelming consideration is given to proprietary and scientific interests of those who carry out research and commercially develop biotechnological inventions, over the general interest in safeguarding open genetic knowledge and the individual and collective rights of donors of genetic samples. Domestic legislation<sup>104</sup> and case-law<sup>105</sup> confirms this trend. This is clearly the result of a widespread

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<sup>99</sup> A mandatory requirement of disclosure of source and origin of genetic resources in the TRIPS agreement and WIPO treaties is advocated *de lege ferenda* by F. Abbott, “Patents Biotechnology and Human Rights”, in this volume.

<sup>100</sup> A more radical view holds that genes are not patentable because by allowing such property rights we would permit private constructive control of the genetic code, since “... the gene is the static chemical compound and the dynamic template executed through the genetic code”, E. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, *Tennessee Law Review*, vol. 71, 2004, p. 707.

<sup>101</sup> Obviously, this may be the most difficult issue to address, given the sensitive nature of creating new institutions competent to administer funds in the common interest. However, one should keep in mind that institutions or fora already exist that might perform the function of trustees of the common genetic heritage of humankind: they are: 1) the International Sea Bed Authority, which, under Article 157 of the LOS Convention (*supra*, note 25) shall have such powers “as are implicit and necessary for the exercise of those powers and functions with respect to activities in the Area”; 2) the Antarctic Treaty Consultative Meeting, with regard to the genetic resources of Antarctica (see Vigni, *cit.*, note 44); and 3) the Biodiversity Convention (*supra*, note 1).

<sup>102</sup> See *Universal Declaration on the Human Genome and Human Rights*, *supra*, note 6.

<sup>103</sup> *Ibid.*, article 4.

<sup>104</sup> For reference to domestic legislation, see R. Brownsword, in this volume.

assumption that it is in the interest of scientific progress not to inhibit bio-technological experimentation by considerations of proprietary or privacy rights of the individuals or groups who have provided genetic material.

But is this assumption correct? Besides the radical critique moved to gene patenting, based on the argument that DNA does not fulfil the requirements of patentability because it occurs in nature, it is the emerging judicial practice in this area to cause some doubts. Rather than advance the public interest in the progress of knowledge and the enhancement of health, gene patenting may easily become a tool of enclosure of knowledge and an obstacle to the legitimate pursuit of health care by patients. In the recent case of *Greenberg v. Miami Children Hospital*, several families affected by a rare genetic disorder (Canavan's disease) had provided research institutions with their children's tissue samples for research purpose and in the legitimate expectation that genetic tests could be developed in order to diagnose and treat the disorder. The Hospital identified the gene mutation which caused the disease, patented the gene, and started charging fees on tests for the syndrome. This led the same families that had provided the genetic material necessary to identify the origin of the disease to being charged fees for the tests of their members. Is this correct? I doubt it is. And more clearly this outcome would not be consistent with a general principle of justice and equity if those who provided the biological samples to discover the genetic cause of the disease were left without access to the tests because of a financial obstacle to paying the fees. The response of the affected families in this case is quite interesting and reveals a sort of Pavlovian reflex in terms of propertization of the legal thought on the matter. Rather than arguing on the basis of a claim to open knowledge and fundamental right of access to health care, the families chose to base their complaint on the alleged breach of their proprietary data and misappropriation of ownership rights over their biological samples. These claims failed and the United States court decided that the defendant hospital was under no obligation to disclose the financial interests involved in the prospect of a commercial exploitation of the results of the genetic trials.<sup>106</sup>

## 10. Conclusions

The foregoing analysis shows that, at least a preliminary answer can be given to the question we have raised at the beginning of this paper whether it is useful to look at the challenges posed by genetic science in the perspective of human rights. The answer is clearly yes, it is useful and necessary. The current asymmetry of knowledge and power between scientific and technological actors, on the one hand, and the traditional institutions of government and of civil society, on the other, cannot be redressed by a concurrent race to the privatization and propertization of genes, the human body, plants, new discoveries and everything else. A more rational approach is that based on the universally shared value of international human rights. In this paper, we have identified the role that in this area can be played by human dignity, non-discrimination, self-determination of peoples and groups, the integrity of the human body and the equitable balancing of property rights and the general interest in the

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<sup>105</sup> See the famous case of *Moore v. Regents of the University of California*, 793 P2d 479, as well as *Greenberg v. Miami Children's Hospital Research Institute, Inc.* 208 F. Supp. 2d 918 cited, by R. Brownsword, in this volume.

<sup>106</sup> *Greenberg v. Miami Children's Hospital Research Institute Inc.*, 264 F. Supp. 2d 1064, Southern District, Florida, 2003. for a precedent, *Moore v. Regents of the University of California*, 793 P. 2d 479, California 1990.

advancement and diffusion of knowledge. In this respect an important role can be played by Article 15 of the International Covenant on Economic Social and Cultural Rights, which proclaims the rights “of everyone to enjoy the benefits of scientific progress and its applications”. This provision calls for the maximization of open knowledge and of the benefits of its application, rather than support the tendency toward extreme forms of ownership in intellectual property, on the one hand, and in the sources of genetic material, on the other. But this is a long term project. In the short term it may not be so easy. This is an epoch that celebrates the myth of property. And as has been lucidly put: “a time is marked not so much by ideas that are argued about, but by the ideas that are taken for granted...the idea of property is just such a thought, or better, just such a non-thought; when the importance and value of property is taken for granted; when it is impossible, or at least for us, very hard to get anyone to entertain a view where property is not central; when to question the universality and inevitability of complete propertization is to mark yourself as an outsider. As an alien.”<sup>107</sup> In the field of biotechnology the human rights discourse is a way to question this central thought. It is a way to avoid becoming an alien.

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<sup>107</sup> L.Lessig, *The Architecture of Innovation*, 2001, as cited by A. Rouvroy, *supra* note 72, p. 47.