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## **Report of the IBC on Ethics, Intellectual Property and Genomics**

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Division of the Ethics of Science and Technology

# CONTENTS

I. THE PROBLEM

II. THE INTERNATIONAL FRAMEWORK

III. APPROACH

IV. THE WAY FORWARD

V. CONCLUSIONS

*Annexes*

- 1) *Composition of the IBC Working Group on Ethics, Intellectual Property and Genomics*
- 2) *« Ethics, Intellectual Property and Genomics: Analysis of International and National Texts » (SHS/HPE/2001/CONF-804/3 Rev.1 of 16 July 2001)*

## I. THE PROBLEM

1. Immediate background: At the initiative of its Director-General, Mr Koïchiro Matsuura, UNESCO held from 30 January to 1 February 2001 in Paris an International Symposium on “Ethics, Intellectual Property and Genomics”, at the closing session of which the participants asked UNESCO to ensure an appropriate follow-up. The International Bioethics Committee (IBC) was entrusted with this task. A Working Group was therefore set up and met at UNESCO Headquarters on 13 and 14 June 2001 (see Composition of the Working Group in Annex I).
2. History: The history of intellectual property can be traced back to classical times. Modern legal protection was given by monopolies granted by the Crown in England and France 400 years ago. The first international convention of relevance was the Paris Convention for the Protection of Intellectual Property of 1883. Since then there have been many municipal, regional and international legal developments that together create the network of the world’s intellectual property laws. Instead of more appropriate legal regimes being developed for recent technologies, generally the existing law of intellectual property has been pressed into service, sometimes with less than perfect results.
3. Subject Matter: The genome is not confined to the human genome. Genomics extends to the study of animal, microbial and plant genomes. However, the IBC has decided to single out for primary attention issues presented by patenting and the human genome. This is consistent with the focus of UNESCO’s Universal Declaration on the Human Genome and Human Rights (1997). Nevertheless, some of the conclusions of the IBC will also be relevant, by analogy, to patenting of other genome sequences.
4. Basic Problem: The fundamental issue is how to secure the benefits of the first draft of the human genome sequence for the service of humanity as a whole. The publication of this first draft stimulates consideration of this issue and gives it an element of urgency.
5. Timing: The publication of the first blueprint of the human genome occurred in February 2001 in *Science* and *Nature*<sup>(1)</sup>. The genome sequences of many other species have also been published in recent times.
6. Context: The problem must obviously be considered in the context of an accurate understanding of the international, regional and municipal laws on intellectual property and knowledge of practical developments involving the invocation of such laws. An analysis of existing international and national texts is provided in Annex II.
7. What is happening: There has been an explosion in the number and variety of applications for patents in respect of the human genome in the United States of America, Europe and elsewhere. Especially controversial have been patents granted in some countries on primary sequences. These developments have given rise to a significant international controversy which the UNESCO Symposium addressed.

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1. *Science* (2001) 291, 1155 ; *Nature* (2001) 409, 813.

8. Benefits of intellectual property: The law on intellectual property serves useful purposes, has a foundation in ethical principles and universal human rights and often contributes to the benefit of humanity. The law protecting intellectual property can facilitate the investments necessary for large and expensive steps in scientific and technological research. Intellectual property protection can also provide an incentive to scientific and technological research and ensure the disclosure of the outcomes of such research to the world at large. Converting discoveries about the human genome from scientific data to beneficial therapies or useful tests is potentially problematic and expensive. Already private investment in genomics has produced important advances that have accelerated human knowledge that will ultimately be to the benefit of humanity. The IBC recognises these potential advantages of intellectual property protection and the reality that legal protection exists and plays an important part in municipal, regional and international law and in the national, regional and international economies.

9. Concerns:(a) Change in the tradition of open science:

Until very recently, almost universally, pure scientific research was substantially funded publicly. It operated in a culture in which individual scientists, universities and foundations did not seek or obtain financial benefits from primary scientific advances. This explains how, between 1920 and 1970, great progress was made in pharmaceutical developments (e.g. penicillin and other antibiotics and vaccines) with little demand for intellectual property protection. This contributed greatly to improvements in public health. In the 1980s, things began to change. An illustration of the change has recently come to light in the development of HIV therapeutic drugs. Although essential to the right to life and health of millions, the intellectual property protections effectively made such drugs mostly unavailable except in developed countries. This led to a public outcry, development of generic drugs, abandonment of court action taken to enforce intellectual property rights in South Africa and widespread public demand for removal of some intellectual property protections in respect of these therapies. Although they are not strictly developments of genomics, they present an illustration of dissatisfaction with the current international, regional and municipal legal regimes as they affect pharmaceuticals and tests vital to human life and health.

(b) Change in the balance of public and private research investment:

There is a concern that a decline in public funding for general research is increasing the proportion of research funded by the private sector and hence changing the priorities of that research. Most of the early work on the Human Genome Project itself was, directly or indirectly, publicly funded in many countries. It would not have started without those funds and the insatiable curiosity of scientists unimpeded by large numbers of intellectual property protections.

- (c) Character of genome as intimate to the human species:  
Never before in science have individual human participants and groups been so closely involved in, and necessary to, scientific and technological advances. The genomic sequence, out of which tests and therapies are developed, begin in every case with a sample provided by an individual human being or samples provided by a group of the population concerned.
- (d) Diversion of research priorities:  
Concern also exists at the potential diversion of research priorities into particular areas by reference to maximum financial rewards rather than those that reflect the greatest human needs.
- (e) Premature protection:  
Concern exists about the rapid growth of intellectual property protection, at a time when genome science is in its infancy, with the consequent risk that this coincidence will impede the flourishing of free and uninhibited research that should be possible at this time to take full advantage of the dramatic breakthrough in knowledge about human bio-sciences.
- (f) The novelty requirement:  
Isolation and sequencing of DNA and translation of such DNA sequences to proteins, and identification of functions by computer analysis have, to some extent, removed “novelty” (one of the traditional basic criteria for patentability).
- (g) Uncertainty about the genome in its “natural state”:  
A question is posed as to how far the “natural state” of the human genome extends. This is referred to in Article 4 of the Universal Declaration on the Human Genome and Human Rights. The answer to that question is still uncertain. This is especially due to the complexity and evolving character of the concept. It can thus be subject to various interpretations. No settled interpretation yet commands universal or general acceptance.
- (h) “Downstream” use of scientific knowledge for new utility subsequently revealed:  
A specific concern is a tendency to seek and secure patent rights over genomic sequences of uncertain future utility, leading to a premature accumulation of intellectual property rights which may have a consequence of discouraging unimpeded research in respect of particular genes or in the proteins which they express, because of awareness of a prior intellectual property right with respect thereto. The grant of patents in terms that are unnecessarily wide will have large consequences “downstream” as the subsequent significance of a particular gene – or that gene in interaction with others or with environmental factors – comes to be known.

(i) The duration of present intellectual property:

The duration of patent protection of 20 years as a universal rule is arguably excessive having regard to the context of genomic sequences and the rapid advance of knowledge about them.

(j) Implications for developed and developing countries alike:

The intellectual property protections already granted and applied for will potentially add greatly to the national health budgets of developed countries. The concerns about the consequences of intellectual property rights have obvious implications for developing countries. They will be burdened by the costs of licensing fees which will be applicable for many years. Such costs may render beneficial therapies or useful tests effectively out of the reach of such countries and most of their people. However, such concerns are not confined to developing countries.

(k) Analogous issues in other spheres:

The problems raised by the application of the present intellectual property regime to rapidly evolving scientific fields were discussed, *mutatis mutandis*, by the COMEST Sub-Commission on the Ethics of Outer Space, in particular concerning inventions, processes and products of the space industry<sup>(2)</sup>.

(l) Equitable benefit sharing:

Concern has been expressed about the lack of effective and fair benefit-sharing with many of the developing countries, from which genetic materials are commonly taken and technology transfer to such countries.

(m) Conflicting international rights:

The IBC observes that there may be conflicts between the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPs Agreement) and the realisation of internationally protected economic, social and cultural rights<sup>3</sup>. In this regard it refers to Resolution 2000/7 of 17 August 2000 of the Commission on Human Rights which identified these conflicts as, “*inter alia*, impediments to the transfer of technology to developing countries, the consequences for the enjoyment of the right to food of plant variety rights and the patenting of genetically modified organisms, ‘bio-piracy’ and the reduction of communities’ (especially indigenous communities’) control over their own genetic and natural resources and cultural values, and restrictions on access to patented pharmaceuticals and the implications for the enjoyment of the right to health”.

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2. See the Report of the Sub-Commission on the Ethics of Outer Space of the UNESCO World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) (July 2000), available from the Secretariat and on the Internet ([www.unesco.org/ethics](http://www.unesco.org/ethics)).

3. See in particula Annex II.

## **II. THE INTERNATIONAL FRAMEWORK**

The foregoing concerns of the IBC must be viewed in an international framework in which an increasing number of initiatives are being taken relevant to the provision of intellectual property protection in respect of human genome sequences. Many of these initiatives have emphasized the imperative need to share the remarkable scientific advances with all of humanity. Amongst these have been:

1. Universal Declaration on the Human Genome and Human Rights, November 1997;
2. Budapest Declaration on Science and the Use of Scientific Knowledge (non limitation of public funding of sciences), July 1999;
3. Clinton/Blair Statement, 14 March 2000;
4. Statement of the Director-General of UNESCO, May 2000;
5. Statement of G-8 Summit, July 2000;
6. Resolution 2000/7 of the United Nations Sub-Commission on Human Rights, 17 August 2000;
7. Millennium Declaration of Heads of State, September 2000;
8. UNESCO Symposium on “Ethics, Intellectual Property and Genomics” (30 January – 1 February 2001);
9. Resolution 2001/71 of the United Nations Commission on Human Rights, 25 April 2001;
10. Resolution of European Assembly, text adopted on 25 April 2001;
11. Statement of the Director-General of WHO to World Health Assembly, 14 May 2001;
12. Recommendation 17 of the Second Session of the Intergovernmental Bioethics Committee of UNESCO (IGBC), May 2001.

## **III. APPROACH**

### **(A) General Framework**

It is appropriate to start an approach to the problem under consideration by taking into account a number of general principles:

1. The principles of the Universal Declaration of Human Rights (1948) (e.g. right to health protection and health promotion, right to the protection of the moral and material interests resulting from any scientific production) and the International Covenant on Economic, Social and Cultural Rights (1966);
2. The principles of the Universal Declaration on the Human Genome and Human Rights (1997), noting especially:

#### *Article 1*

The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

*Article 4*

The human genome in its natural state shall not give rise to financial gains.

*Article 19*

a) In the framework of international co-operation with developing countries, States should seek to encourage measures enabling:

- i) assessment of the risks and benefits pertaining to research on the human genome to be carried out and abuse to be prevented;
- ii) the capacity of developing countries to carry out research on human biology and genetics, taking into consideration their specific problems, to be developed and strengthened;
- iii) developing countries to benefit from the achievements of scientific and technological research so that their use in favour of economic and social progress can be to the benefit of all;
- iv) the free exchange of scientific knowledge and information in the areas of biology, genetics and medicine to be promoted.

b) Relevant international organizations should support and promote the initiatives taken by States for the abovementioned purposes.

3. The main task of the IBC being the promotion of bioethical thought, it should be recalled that ultimately law serves the interests of the people and should reflect their ethical concerns.
4. An acceptance of the value of intellectual property law should also guide an informed response, including acceptance of the ethical values which intellectual property law is designed to uphold.

(B) Particular Ethical Principles

In addition to the foregoing general principles, there are a number of particular principles specific to the human genome that need to be kept in mind in framing a response to the foregoing concerns:

1. The importance of [free] access to the benefits flowing from scientific knowledge in accordance with Article 27 of the Universal Declaration of Human Rights. It is vital to insist on the transparency of basic science and to a certain extent, Article 27 of TRIPs Agreement could impede this. Arguably, it conflicts with universal ethical principles and with the Universal Declaration of Human Rights and with the Universal Declaration on the Human Genome and Human Rights. This conflict must be resolved.
2. The importance of equitable benefit-sharing, which has a dual aspect:
  - (i) It involves sharing the benefits of research with the contributor of genetic materials and the populations and countries that participated in that research; and



- (ii) It also involves sharing the benefits with individuals and groups more generally to whom the research is relevant. To some extent presently operating laws, regulations and funding guidelines (e.g. National Institutes of Health Guidelines in the United States of America) promote observance of ethical standards but these need to be strengthened and made more clear and universal in their application.
3. The promotion of international co-operation with developing countries, including technology transfer within the framework of Article 19 of the Universal Declaration on the Human Genome and Human Rights, needs to be translated into action and current intellectual property law does not appear to sufficiently promote this.
4. The regulation of aspects of the human genome (including intellectual property aspects) should be the subject of genuine democratic debate in all countries. This should involve the people generally, indigenous peoples in particular; also special populations and groups subject to particular genetic conditions so that they understand and truly participate in decisions concerning genetic diversity and their future. The IBC recognises that much research on population groups will benefit such groups or the members thereof and patients everywhere subject to genetic conditions disclosed by such research.
5. Informed consent is now a universal ethical principle in research involving human beings, including research connected with the human genome, provision of genetic samples, treatment, etc. It is reflected in Article 5(b) of the Universal Declaration on the Human Genome and Human Rights. It should be scrupulously complied with.
6. Ultimately, there is a conflict or tension between ethical principles – those that uphold the right to protection of the creative inventions of the human mind and those that uphold the right to life, the right to health protection and promotion and the solidarity of the entire human family. In the context of intellectual property law it is necessary to resolve this conflict in a just way. The present intellectual property law, municipal, regional and international, falls short of doing this. Hence the IBC turns to consider proposals for future action.

#### **IV. THE WAY FORWARD**

1. The International Bioethics Committee (IBC) welcomes the Director-General's initiative of creating of an inter-agency committee on bioethics with the task of improving co-ordination of the activities of participating organisations, and of considering bioethical issues which should give rise to increased co-operation, such as intellectual property related to genomics. It endorses the hosting by UNESCO of its first meeting in Paris on 17 September 2001. The IBC is fully committed to co-operating with the Director-General in this respect.
2. The IBC supports co-operation and consultation with HUGO, scientists, institutes and corporations involved in genomic research and development.
3. As is recommended in the Guidelines for the Implementation of the Universal Declaration on the Human Genome and Human Rights (Item 3.3.1), UNESCO should promote the establishment, where they do not exist, of national and

regional bioethical bodies to encourage the participation of peoples generally, indigenous peoples and particular population groups in an informed debate about genomic developments. The political decision-makers and institutions, scientific bodies, universities and other institutions of learning, media, civil society organisations and other relevant bodies have a vital part to play in this dialogue which must go beyond consultation and involve active participation by those interested and affected.

4. The IBC supports the call of the Parliamentary Assembly of the Council of Europe for the widest possible participation by citizens in the discussion on the human genome<sup>(4)</sup>. This discussion should extend to the current state of intellectual property law and practice.
5. The IBC supports the expression of concern of the Director-General of WHO as to the potential risk for research on the human genome to widen the knowledge and technology gap between developed and developing countries and to focus on expensive treatments affordable by developed countries rather than readily marketable tests and therapies available more generally. It calls on UNESCO to work in close co-operation with WHO in its initiatives in this regard.
6. The IBC supports the general idea of benefit-sharing, an illustration of which would be the allocation to participating developing countries of a proportion of the net profits made by pharmaceutical companies<sup>(5)</sup>.

## V. CONCLUSIONS

1. The International Bioethics Committee (IBC) believes that, in the framework of its review of TRIPS Agreements, the World Trade Organization (WTO) should clarify that, in accordance with the provision of Article 27(2)<sup>(6)</sup>, the human genome is not patentable on the basis of the public interest considerations set out therein, in particular, public order, morality and the protection of human life and health. All concerned institutions such as WTO and WIPO should be informed of UNESCO's concerns as well as its proposed solutions.
2. The IBC recommends that UNESCO promote urgently the adoption of an international convention on ethical and other issues relating either to intellectual property and genomics, or on living matter including intellectual property and genomics. This Convention would, *inter alia*, clarify that the public interest considerations set out in Article 27(2) of TRIPs Agreement constitute an exception to patentability in respect of the human genome. Alternatively, UNESCO should promote the development of a Code of Conduct addressed to States, natural and juridical persons, and international organisations, by building, *inter alia*, on the public interest considerations included in the TRIPs

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4. Recommendation 15/2 (2001) 1. Para. 9

5. HUGO Ethics Committee Statement on Benefit-Sharing <http://www.gene.ucl.ac.uk/hugo/benefit.html> or "Genetic Benefit Sharing" Vol. 290 *Science* (2000) p. 49

6. Article 27.2 of TRIPs Agreement reads: "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or in order to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law".

Agreement. It should take this initiative in consultation with WTO and WIPO and other relevant interested groups and institutions both to stimulate and promote principled action by such bodies and by the international community.

3. The IBC will keep under consideration the question of an appropriate intellectual property regime either on the basis of its recommendations in paragraphs 1 and 2, or any other basis which takes into account the ethical concerns voiced by the international community and reflected in this Report. While a few members of the IBC had reservations about this conclusion, if no progress is made in this matter, the IBC will at its next session consider the feasibility of recommending that the Director-General of UNESCO propose to the General Conference that appropriate steps be taken towards a global moratorium on the grant of further patents in relation to human genome sequences.
4. UNESCO should consider taking an initiative within the United Nations system towards the establishment of a mechanism, possibly a fund, where necessary to acquire for the benefit of humanity the intellectual property that is privately owned in relation to human genome sequences. This mechanism or fund might be developed by analogy with the World Fund created by WHO for HIV/AIDS therapy and in a way similar to the mechanism or fund proposed by the IBC Report on Solidarity and International Co-operation between Developed and Developing Countries concerning the Human Genome.
5. The advances in genomics are occurring so rapidly that the subject matter of this Report should be kept under constant attention by the IBC. This Report should be reviewed within 1 year of its adoption so that the attention given to the proposals may be assessed and so that any changes made necessary by advances in scientific knowledge or technology can be taken fully into account. The IBC emphasises that it regards the subject matter of this report as both vitally important and extremely urgent. Without action, the current municipal, regional and international intellectual property regimes will continue to apply. More patents will be sought and granted in accordance with such laws. The spiral of patents in relation to human genome sequences will expand. The costs of future therapies and genetic tests will become prohibitive for most human beings and nations. Science will be restrained instead of encouraged. And a remarkable opportunity for humanity to act in a way defensive of the entire human species will be lost.



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**COMPOSITION OF  
THE WORKING GROUP OF THE IBC  
ON ETHICS, INTELLECTUAL PROPERTY AND GENOMICS**

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***Ethics, Intellectual Property  
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**Analysis of international and national texts**

Division of Human Sciences, Philosophy and  
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## Table of contents

<b>Summary</b> .....	1
<b>Introduction</b> .....	3

### Part one – International Regulations

#### A. UNIVERSAL ORGANIZATIONS

1) The World Intellectual Property Organization (WIPO) .....	5
2) The World Trade Organization (WTO) .....	7
3) The Convention on Biological Diversity (CBD) .....	9
4) The United Nations .....	11
5) United Nations Educational, Scientific and Cultural Organization (UNESCO) .....	12

#### B. REGIONAL ORGANIZATIONS

1) The European Patent Office (EPO) .....	14
2) The European Union (EU) .....	15
3) The Council of Europe .....	21
4) The Organization for African Unity (OAU) .....	23
5) The Eurasian Patent Organization (EAPO) .....	25

### Part Two – National Regulations

#### A. States least favorable to human genome patentability

1) Austria .....	26
2) Czech Republic .....	26
3) Finland .....	26
4) France .....	27

#### B. The most common intermediate stances

1) Belgium .....	27
2) Canada .....	27
3) Italy .....	28
4) Republic of Korea .....	28
5) Switzerland .....	28
6) Taiwan .....	29
7) United Kingdom .....	29

#### C. States most favorable to genome patentability

1) Australia .....	29
2) Japan .....	30
3) United States of America .....	30

#### D. Developing countries and the quest for new rules

1) The Andean Pact .....	32
2) Costa Rica .....	32
3) Peru .....	33
4) Venezuela .....	33

### Conclusions

1) The most controversial aspects .....	34
2) Suggested solutions .....	34



## Summary

Following a brief description of the patent system (Introduction), this study presents a compilation and analysis of legislation and/or recommendations adopted nationally and internationally in the field of what is known as the 'patentability of living organisms'. Although these texts aim to regulate human genome patentability, they do not necessarily address the issue in such specific terms. When such is the case analyzing provisions relative to the patentability of living organisms in general (micro-organisms, plants, and more particularly animals) allows for the identification of relevant general principles, and their subsequent applicability to human beings.

The first part of this study analyzes texts and recommendations, which have been adopted internationally. As regards universal organizations, the two most relevant texts are WTO's Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS), and the Convention on Biological Diversity (CBD) adopted within the framework of the United Nations system.

Human genome issues are not addressed specifically by these two texts, nor are they specifically ruled out. Some have therefore felt that they open the door to possible human genome patenting. Others think that this will in the end hinge on how the two texts are interpreted, knowing that in the framework of WTO, interpretation is likely to be mainly based on economic criteria.

The World Intellectual Property Organization (WIPO) has decided to set up a committee on intellectual property and genetic resources, which would *inter alia* take into account the interests of developing countries. The United Nations Commission on Human Rights, concerned by the possible impact of intellectual property on human rights, feels that such rights are not sufficiently taken into consideration within the TRIPS Agreement. Finally, UNESCO has adopted the Universal Declaration on the Human Genome and Human Rights, stating that the human genome is 'the heritage of humanity'.

At the regional level, Directive 98/44 on the legal protection of biotechnological inventions, adopted by the European Union (EU), is the only international instrument expressly regulating human genome patenting. This directive, the formulation of which is ambiguous, has been much criticized insofar as it does open the door to the patenting of human genes. The European Patent Office (EPO), which issues patents in Europe under the 1973 Munich Convention, has adopted a very favorable approach to the patentability of living organisms in general and human genes in particular, although the Convention, per se, does not authorize such patenting. Conversely, the Council of Europe is opposed to the patentability of living organisms in general, and a fortiori to the patentability of human genes. The Council intends to adopt shortly measures specific to this field.

The Organization of African Unity (OAU) which groups 53 countries from the African continent, has asserted a strong moral stance by adopting a 'model law' based on the Convention on Biological Diversity. This model law suggests a form of protection which differs from the intellectual property rights' system, in that it is less exclusive and opposes patenting for all life forms. The Eurasian Patent Organization (EAPO) has not specifically addressed the issue of human genome patentability. The Organization is too new for any conclusion to be drawn from its policy.

The second part of this study reviews regulations, patent office policies and the opinions published by national ethics committees, starting with those positions that are least favorable to human genome patentability, the Czech Republic and France being two cases in point, and moving on to those which are most favorable, such as the United States of America. Some developing countries, such as Peru, have taken a different stance: that of protecting their vast genetic resources - plant, animal, or human - from developed countries' bioprospection activities. In so doing, they find inspiration, *inter alia*, in the Convention on Biological Diversity.

# Introduction

Managing and using genetic resources and sharing the benefits that derive therefrom are issues of current concern for decision-makers in very diverse fields: food and agriculture, biological diversity, biotechnological innovation and regulation, human rights, etc. In all such fields, issues of intellectual property have come to the fore.

Regarding the human genome, these issues seem to involve values such as the dignity attached to human beings, their legal status, and their possible property value. What is at stake is whether those genes that make up human beings are the 'shared heritage of humanity' or whether, for the sake of research and progress in medicine, they can somehow have property rights, monopoly rights, or commercial development rights attached to them. What is also at stake, for that matter, is determining whether this is a fallacious dilemma, insofar as medical progress could occur through other funding schemes, which might be more favorable to health policies designed for the common good. How are such concerns addressed by regulations adopted both nationally and internationally? What are patents?

## Patents

Intellectual property rights include copyright (for databases, works, etc) and industrial property rights (patents, protection of plant varieties, brands, designs, models, etc.). As a rule, four conditions must be met for patent granting: novelty, innovativeness, applicability, and industrial reproducibility. Patents confer exclusive rights, for periods of about 20 years, over the patented product or process. Patents prohibit third parties from manufacturing, using, selling, or exporting the patented product or process. Patent holders may, but are not obliged to grant licenses against the payment of fees which are often very high. Inventions have to be disclosed to patent examiners in considerable detail.

## Harmonisation of intellectual property rules

Geographical extension is a major issue. In the absence of international commitments, protection does not extend beyond the borders of the State which has granted a patent. The United States of America has adopted a policy of strong invention protection, further strengthened by decisions taken by the US Patent and Trademark Office. Not only does this Office grant patents on living organisms without exception; it also happens to grant 'broad' patents (covering both process and product). The European Directive on the legal protection of biotechnological inventions, passed in October 1998, harmonizes patent recognition in all of the Union's member states and sets rules favorable to human genome patentability, following the US example on this count.

## Patent types

- Product patents: covering all possible product uses, including those which are still unknown.
- Use patents: granting protection only for such use as defined in the patent application.
- Process patents: granting protection to processes, regardless of the product involved. Do not confer protection to the same invention produced via other processes.

The US Patent Office grants patents within three years of patent application submission, whereas in Europe, the corresponding timelag is 18 months, as of the day a patent application is submitted. These timeframes are designed to allow patent offices to research applications, in order to verify that the invention submitted is indeed new, not obvious, and lends itself to industrial applications. In the case of inventions derived from natural products, some have urged that submission review include the two following prerequisites:

- the source of said natural product must be mentioned;
- proof of prior voluntary informed consent on the part of those from whom the product has been taken must be provided.

States are however far from having reached a consensus on the legitimacy or the conditions applicable to human genome patenting. Some, but not all have called for the two aforementioned prerequisites. Some have excluded a priori all forms of human genome patenting, while others allow it without requiring donor consent. The TRIPS Agreement, which could have set clear and universally applicable rules in this field, does not provide any indication on this. Other texts, other organizations have suggested solutions of varying degrees of originality.

## *Part One - International Regulations*

### A. UNIVERSAL ORGANIZATIONS

#### 1) The World Intellectual Property Organization (WIPO)

Laws on intellectual property were initially national, but the international community gradually negotiated international agreements in this field. The World Intellectual Property Organization (WIPO) is the specialized United Nations agency responsible for the promotion of intellectual property worldwide. It administers 20 conventions and treaties in the field of intellectual property. Two conventions concern patents:

- the 1883 **Paris Convention** for the protection of intellectual property, last amended in 1979;
- the **Patent Cooperation Treaty** signed in Washington in 1970, last amended in 1984.

These treaties are obviously too old to provide answers to questions regarding living organism patentability. In view of the legal vacuum of conventions subject to its administration in this respect, WIPO was recently requested by its Member States to undertake exploratory groundwork with a view to achieving better understanding of issues of intellectual property regarding genetic resources.

The main outcome of this effort, which was initiated in 1998, has been the decision to set up a 'Committee on intellectual property and genetic resources, traditional knowledge, and folklore'<sup>1</sup>. The Committee has held its first session from 30 April to 3 May 2001, in Geneva<sup>2</sup>. The first major topic that has been considered, designated as topic A, is 'Access to Genetic Resources and Benefit-Sharing', mainly in the context of North-South relations. During this first meeting, the Committee has discussed on the proposals made by WIPO in the framework of topic A, proposals that come under four categories:

A1) *Contractual agreements for access to genetic resources.* Access agreements for genetic resources raise questions on the role of intellectual property rights in respect of ensuring control over ex-situ use of genetic resources, technology transfer and joint research and development, the exploration of the possibility of joint ownership of intellectual property rights, ensuring continued customary use of genetic resources, etc.

WIPO is contemplating the development of 'best contractual practices', guidelines and model intellectual property clauses for the material transfer agreements and other access agreements.

A2) *Legislative, administrative and policy measures.* Issues arising in the development of national and regional access legislation include the role of intellectual property rights regarding: prior informed consent procedures; ensuring the recording of ownership interests in inventions that arise from access to or use of genetic resources; transfer of and access to technology in the context of benefit-sharing; and joint research and development as a form of non-monetary benefit-sharing.

A3) *Multilateral systems.* A number of different provisions may be contemplated: possible intellectual-property-based benefit-sharing mechanisms; the acquisition of intellectual property rights over genetic resources which are then placed in the multilateral

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1. 'Matters concerning intellectual property and genetic resources, traditional knowledge and folklore', WO/GA/26/6, WIPO General Assembly, 26th session, 25 September – 3 October 2000, Geneva.

2. The draft report of the first session of the Intergovernmental Committee is available at WIPO's headquarters.

system; access under the multilateral system to genetic resources covered by intellectual property rights; transfer of and access to technology under the multilateral system; and the rights of holders of traditional knowledge associated with genetic resources placed in the multilateral system.

A4) *The protection of biotechnological inventions, including certain related administrative and procedural issues.* Intellectual property issues in the field of biotechnology include: licensing and other issues related to the use of rights in biotechnological inventions; administrative and procedural issues related to the examination of patent applications directed at biotechnological inventions; the relationship between patents and other forms of intellectual property protection for biotechnological inventions; and certain aspects, related to ethical and environmental issues, animal and human health.

The Committee furthermore wants to look into the need to extend the intellectual property rights approach. Many applications, needs and expectations in this field cannot be accommodated within the framework of intellectual property as it is currently defined. In some cases, responses to such requests for protection could stem from a development of the intellectual property approach. In others, intellectual property could be made to evolve towards the definition of new *sui generis* schemes tailored to the subject matter to be protected, ie genetic resources, along the lines of previous developments aiming to protect plant varieties.<sup>3</sup> One could also contemplate extending intellectual property by adapting existing schemes so as to include, to the largest extent possible, subject matter that is currently not covered.

The Members of the Intergovernmental Committee also reacted to the five tasks proposed by WIPO in its working document<sup>4</sup>, concerning concrete activities that the Committee could lead. The next meeting of the Intergovernmental Committee is to be held from 10 to 14 December 2001.

### Basic Features of the Patent System

The lack of protection and the acts of ‘bio-piracy’ denounced by holders of biological and genetic materials seem both to stem from inappropriate regulation. In order to put an end to a number of practices, which lead to outcomes detrimental to such holders of materials, WIPO has already underscored the significance of a number of conditions that cannot be removed from the patent system:

- 1) **Natural products:** patents are granted for the sole purpose of protecting inventions, i.e. technical solutions devised by man. Patents must therefore not be granted for subject matter as can be found in nature, as such subject matter is not the product of human intervention but a simple product of nature. Confirming this consensus more explicitly at the international level might help avoid situations leading to the granting of patents for micro-organisms, plants or other biological elements found in nature.
- 2) **Legitimate use and exploitation of genetic resources.** The Committee intends to study to what extent illegitimate access to such resources may have an impact on patent granting for inventions produced on the basis of material acquired illegally or on the validity of patents thus granted. It may also prove necessary to define the principles of international harmonization of such criteria so that illicit deeds done in a given country may actually be acknowledged as such and sanctioned in other countries as well. Failing such provisions, ‘bio-piracy’ would be sanctioned in those countries

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3. UPOV, International Convention for the Protection of New Varieties of Plants. This *sui generis* system was set up in 1960 and protected inventors’ intellectual property rights while providing free access to plant varieties. After many modifications, this system has gradually moved ever closer to that of patents.

4. « Matters concerning intellectual property and genetic resources, traditional knowledge and folklore – an overview », WIPO/GRTKF/IC/1/3, March 16, 2001.

which have been the victims of illicit deeds, but not in those where the products derived from the illicit deed are commercially exploited.

- 3) **Streamlining of revocation and claims filing procedures:** in view of the above, it would be desirable to consider providing streamlined and cheaper patent revocation procedures for patents granted for inventions derived from biological or genetic resources illicitly obtained in a foreign country, as well as for rights pertaining to the relevant resources and knowledge.

## WIPO and WTO

Multilateral trade negotiations within GATT led to the creation of the World Trade Organization (WTO) on April 15, 1994, as well as to the conclusion of the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS), which came into force on January 1, 1995. TRIPS Treaty provisions are directly complementary to the international treaties administered by the WIPO Secretariat.

On January 1, 1996, an agreement between WTO and WIPO came into force. It provides for cooperation activities concerning the implementation of the TRIPS Agreement, and regarding, for example, the notification of legislation and regulations, as well as for legal and technical assistance and technical cooperation activities targeting developing countries.

## 2) The World Trade Organization (WTO)

Intellectual property today is one of the controversial areas of international trade: harmonization of the intellectual property system has made it possible to extend patent protection worldwide, thus prohibiting the production or marketing of given products or processes, and potentially generating a global demand for imports of these products and processes. Many authors have therefore compared this system to a monopoly situation.

The World Trade Organization (WTO), the successor to GATT, has adopted an Agreement on the Trade Related Aspects of Intellectual Property Rights, which is a milestone in the history of intellectual property because of its exceptionally broad scope. On the one hand, this Treaty seems to be the first and only treaty to cover all aspects of intellectual property (literary and artistic creations, inventions with industrial applicability and marketing processes.) On the other, it is addressed not only to Member States, but also to their citizens (Article 1, § 3), who may invoke the Agreement in their national courts of law (direct effect) This system has been described by UNDP as ‘introducing an enforceable global standard by linking intellectual property rights with trade, making them binding and enforceable through the World Trade Organization processes’<sup>5</sup>.

The explicit goal of the Agreement is to subject all WTO Member States to the same, harmonized legal system with respect to intellectual property rights, so as to enhance trade. Although the TRIPS Agreement purports to introduce no changes whatsoever to the compulsory nature, for its Member States, of international conventions to which they may be party, its superiority to the WIPO system is quite obvious, and stems from the various control bodies it has put into place, as well as from the specificity of obligations described.

### Exceptions to patentability: Article 27, § 2

The only inventions that can be excluded from patentability are those that are contrary to ordre public or to morality, so as to protect human and animal health and life, and preserve plants and the environment. This is a very general provision, which certainly does not exclude patentability of human genes, no more than it excludes biomedical technologies such as cloning. Advocates of the TRIPS agreement consider this exception to be sufficiently broad,

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5. Human Development Report, UNDP, 2000, box 4.9.

whereas its critics claim that it provides no guarantee whatsoever against the patenting of living organisms, especially in light of Article 8, which authorizes the adoption of appropriate measures, 'provided that they are consistent with the provisions of this Agreement', that may be needed to prevent the abuse of intellectual property rights by rights holders.

Furthermore, there are no waivers for chemicals or pharmaceutical products, and this can have serious repercussions on the rights to health and the rights of indigenous peoples. So far, the national laws of many developing countries, such as China, Egypt, or India have intentionally excluded drugs from product patent protection (allowing only process patents) to promote local manufacturing capacity for generic drugs and to make drugs available at lower prices. The move from process to product patents introduced under the TRIPS Agreement dramatically reduces the possibilities for local companies to produce cheaper versions of important life-saving drugs, such as those for cancer and HIV/AIDS.

***TRIPS Agreement Article 27- Patentable Subject Matter***

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.<sup>6</sup> (...).
2. Members may **exclude** from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect **ordre public** or **morality**, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also **exclude** from patentability:
  - a) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals;
  - b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

As for **indigenous peoples' resources**, under the TRIPS agreement all WTO Member States must now authorize patents on microorganisms, as well as on microbiological and non-biological processes. Products and processes have thus been 'reinvented' and patented, which derive from the traditional knowledge some communities have been passing on since the dawn of time. This is what has led to the patenting not only of some of the curative features of curcuma or other plants, but the NIH even attempted to patent a cell culture derived from the blood of a Hagahai, who carried, as do all the members of that tribe, a virus similar to that associated with leukaemia. These patents gave rise to considerable controversy, and were ultimately revoked.

The TRIPS agreement mainly benefits technologically advanced countries. According to estimates, industrialized countries hold 97 % of all patents, and transnational corporations, 90% of all technology and invention patents. Because of their limited research and development capacity, developing countries hardly benefit from heightened protection as established by the TRIPS agreement

4. For the purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non obvious' and 'useful' respectively.



Article 7, which purports to indicate the objectives of the TRIPS agreement, states that ‘the protection and enforcement of intellectual property rights should contribute to the transfer and dissemination of technology’. This is however just a statement of principle, which is not supplemented by any indication as to how this intellectual property rights protection system could per se enhance the transfer of technology. A number of commentators seem to agree that the TRIPS agreement and the Convention on Biological Diversity are quite similar on at least one point, namely the lack of concrete provisions that could actually help reach the stated goal of transferring technology.

The TRIPS agreement is currently being revised. While the United States of America has requested the elimination of waivers under Article 27, in particular regarding animals and plants, developing countries are seeking a broadening of exemptions concerning the patentability of living organisms.

### 3) The Convention on Biological Diversity (CBD)

The Convention on Biological Diversity was adopted in 1992 in Rio de Janeiro at the close of the UN Conference on Environment and Development. The United States of America has yet to sign it, as US biotechnological industries fear it may limit their activities because of its intellectual property rights provisions. Conversely, developing countries feel that the CBD enhances developed countries’ control over their genetic resources.

On a preliminary basis, it is worth noting that the CBD does not clearly identify its material application scope: it contains no specific reference to human genetic material, be it to include it or exclude it from its purview. Indications may be derived from the definitions given under Article 2 (Use of Terms). Thus, for the purposes of the Convention:

**Genetic material:** means any material of plant, animal, microbial or other origin containing functional units of heredity.

**Biological resources:** includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

**Genetic resources:** means genetic material of actual or potential value.

Although the Convention does not explicitly apply to the human genome, an extensive interpretation can therefore quite clearly lead to such applications. In any event, if the Convention were not to apply to the human genome, the resulting legal vacuum would only confer greater likelihood to the patentability of human genetic material, assuming the inventive step is demonstrated.

As to substance, the Convention’s provisions regarding intellectual property rights are not quite clear. On the one hand, the Convention reaffirms **that States have sovereign rights over their own biological and genetic resources**, and states that Contracting Parties shall take measures, as appropriate, ‘with the aim that Contracting Parties which provide genetic resources are provided access to and transfer of technology which makes use of those resources, including technology protected by patents and other intellectual property rights...’. But on the other hand, the Convention states that in the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights.

## Excerpts from the Convention on Biological Diversity (1992)

### *Article 3. Principle*

**States have the sovereign right to exploit their own resources** pursuant to their own environmental policies...

### *Article 15. Access to Genetic Resources*

2. Each Contracting Party shall endeavour to **create conditions to facilitate access to genetic resources** for environmentally sound uses by other Contracting Parties **and not to impose restrictions that run counter to the objectives of this Convention.**

4. Access, where granted, shall be on **mutually agreed** terms...

5. Access to genetic resources shall be subject to **prior informed consent** of the Contracting Party providing such resources, unless otherwise determined by that Party.

7. Each Contracting Party shall take **legislative, administrative or policy measures**, as appropriate, ... with the aim of **sharing in a fair and equitable way the results of research** and development and the **benefits arising from the commercial and other utilization** of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms..

### *Article 16. Access to and Transfer of Technology*

1. Each Contracting Party undertakes subject to the provisions of this Article to provide and/or facilitate **access for and transfer to** other Contracting Parties of technologies that make use of genetic resources and do not cause significant damage to the environment.

2. In the case of technology subject to **patents and other intellectual property rights, such access and transfer** shall be provided on **terms which recognize** and are consistent with the adequate and effective protection of **intellectual property rights**. The application of this paragraph shall be consistent with paragraphs 3,4, and 5 below.

3. Each Contracting Party shall take ... measures, as appropriate, with the **aim that Contracting Parties**, in particular those that are developing countries, **which provide genetic** resources are provided access to and transfer of **technology which makes use of those resources**, on mutually agreed terms, **including technology protected by patents and other intellectual property rights...**

5. The Contracting Parties, recognizing that **patents** and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure **that such rights are supportive of and do not run counter to its objectives.**

The Convention therefore does not seem to rule out the patentability of living organisms, but its lack of specificity regarding the subject matter protected by intellectual property rights (which could be the technology, the product yielded by the technology, or the gene that is the origin of the process), and its scope (plants, animals or human beings) does not contribute to defining the perimeter of patentability protected under the Convention.

The Convention does not establish whether genetic resources, including the human genome, can be subject to rights of ownership or whether, on the contrary, they are the 'shared heritage of humanity.' It seems rather to state that the decision is a prerogative of individual, sovereign states. This is no doubt a form of protection for developing countries, whose right to oppose, to some extent, exogenous decisions is thus acknowledged, but the legal status of genetic resources remains undefined.

In addition, under the Convention individuals are dependent upon policy decisions made by their States. Companies using intellectual property rights to gain control over genetic resources such as sequences of human genome DNA would not be going against any legal obligation arising from the CBD if the state where said resources were located agreed to this.

In any event, the Convention does not define a universal code of conduct to regulate 'biosprospection' activities, letting the Contracting Parties define 'on mutually agreed terms' (Art. 15, § 4) access conditions for genetic resources. This strictly bilateral approach may well weaken the position of the poorest countries and in the end is tantamount to giving final decision-making powers to governments. Furthermore, the provisions relative to equitable benefit-sharing are very general and do not define a concrete system for the enforcement of this principle.

The only rights actually mentioned and acknowledged are intellectual property rights, which are to be provided with 'adequate and effective protection'.<sup>7</sup> Although the rule seems to provide for access to resources and the sharing of knowledge, with intellectual property rights presented as an exception to this rule, limited to those cases where patents have been granted, intellectual property increasingly covers everything related to plants, animals, and human beings. The exception shall no doubt soon become the rule.

Finally, and even though the CBD appears to be more favorable to the protection of genetic resources than is the TRIPS agreement, it shall prove difficult for States to invoke the CBD to justify violations of their obligations under the TRIPS agreement, because of a principle of international law according to which provisions of earlier treaties are applicable only to the extent that they are consistent with provisions contained in subsequent treaties.<sup>8</sup> By this same token, the principle according to which specific rules prevail over general rules will lead to the upholding of the TRIPS provisions, as these are no doubt more specific and more detailed.

#### 4) The United Nations

The Sub-Commission on the Promotion and Protection of Human Rights of the United Nations has taken a stance on the patentability of living organisms in its resolution on '**Intellectual property rights and human rights**' adopted August 17, 2000 (RES/2000/7). In this resolution, the Sub-Commission gives its opinion on positions taken by a number of international organizations, noting that:

- the **Convention on biological diversity** reconciles the protection of intellectual property rights, the safeguarding of biological diversity, and the promotion of the transfer of technologies;
- the UNDP Human Development Reports 1999 and 2000 identify circumstances attributable to the implementation of the **TRIPS Agreement** that constitute contraventions of international human rights law;
- WIPO is looking into issues of intellectual property concerning indigenous populations;
- that actual or potential conflicts exist between the implementation of the **TRIPS Agreement** and the realization of economic, social, and cultural rights in relation to, *inter alia*, impediments to the transfer of technology to developing countries, 'bio-piracy' and the reductions of communities' control over their own genetic resources, and restrictions on access to patented pharmaceuticals and the implications for the enjoyment of the right to health.

The Sub-Commission goes on to state that:

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7. See, on this topic, the opinion expressed in a CEAS consultants' study for the European Commission, *The relationship between the agreement on TRIPS and biodiversity related issues*, September 2000: 'Essentially, article 16 of the CBD preserves the entitlements of intellectual property owners as they are defined in international law, such as TRIPS'.

8. Art. 30 § 3 and § 4a of the Vienna Convention on the Law of Treaties, 1969.

- the implementation of the TRIPS agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, and that there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS agreement, on the one hand, and international human rights law, on the other.

It therefore requests the **WTO** to take fully into account the existing State obligations under international human rights instruments. It finally requests the **United Nations High Commissioner for Human Rights**, as well as all other relevant international organizations, to continue their in-depth analysis of the human rights impact of the TRIPS agreement.

The 20 April 2001, the Human Rights Commission adopted another resolution on « Human rights and bioethics » (res. 2001/71). Recitals 11, 12, 13, 14, and 15 of the preamble refer to UNESCO's role, to the Universal Declaration on the Human Genome and Human Rights and to pertinent resolutions and decisions of the General Conference and of the Executive Board of UNESCO.

Paragraph 4 invites the Secretary-general :

- to draw up proposals concerning ways to ensure a proper coordination of activities and thinking on bioethics throughout the United Nations system, in view of the 56<sup>th</sup> session of the General Assembly of the United Nations ;
- to consider establishing a working group of independent experts from, inter alia, UNESCO, WHO and WIPO, which would reflect, in particular, on the follow-up of the Universal declaration on the human genome and human rights.

Paragraphs 6 et 7 paraphrase several provisions of the Universal Declaration on the human genome and human rights. Paragraph 8 requests to the Sub-Commission on the promotion and protection of human rights to consider what contribution it can make to the reflections of the International Bioethics Committee on the follow-up of the Declaration. Finally, paragraph 9 requests the Secretary-general to submit a report based on these contributions to the Commission at its fifty-ninth session (March-April 2003).

Following this resolution, UNESCO took the initiative to convene in Paris, on Monday 17 September, - immediately after the 8<sup>th</sup> session of the IBC – an inter-agency meeting, with the participation of the Human Rights High Commissioner, FAO, ILO, WHO, WIPO, WTO, etc., to create the committee mentioned in point 8(ii).

The United Nations Millennium Assembly has also taken a position on these questions in the Millennium Declaration, adopted on 8 September 2000, in particular deciding :

- To encourage the pharmaceutical industry to make essential drugs more widely available and affordable by all who need them in developing countries.
- To ensure free access to information on the human genome sequence.

## 5) UNESCO

UNESCO is one of the first international organizations to have attempted, as of the seventies, work on bioethics. **The Universal Declaration on the Human Genome and Human Rights**, adopted unanimously and by acclamation by the UNESCO General Conference on 11 November 1997 is one of the major achievements of such efforts. The Declaration was endorsed by the United Nations General Assembly on 9 December 1998, in the context of the celebration of the 50<sup>th</sup> anniversary of the Universal Declaration on Human Rights.

Drawn up by the International Bioethics Committee of UNESCO, the Universal Declaration on the Human Genome and Human Rights is the first international normative instrument in the field of bioethics. **Article 1** states that the human genome is the ‘**heritage of humanity**’. The idea is to underscore the fact that research on the human genome and the applications that may stem therefrom bring into play the responsibility of humanity as a whole in the interests of present and future generations. The expression ‘shared heritage of humanity’, which had been initially proposed, was subsequently changed to ‘heritage of humanity’, so as to avoid any interpretation which would consider the human genome as possibly open to collective appropriation, and a fortiori, to individual or private appropriation.

This obviously leads to ruling out human genome patentability. **Article 4** of the Declaration confirms this assertion, insofar as it states:

‘The human genome in its natural state shall not give rise to financial gains.’

UNESCO, in accordance with its calling to further the sharing of knowledge, feels that the simple knowledge of human genes, or partial gene sequences, in their natural state, cannot be subject to intellectual property rights, and that it must be freely accessible to all those involved in research worldwide. This does not rule out the fact that research results may be covered by intellectual property rights.

The Declaration also contains provisions on **scientific cooperation**. Under **Article 18**, States are urged to make every effort ‘to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research (...) particularly among industrialized and developing countries’. **Article 19** invites States to take measures enabling ‘developing countries to benefit from the achievements of scientific and technological research’, and fostering ‘the free exchange of scientific knowledge and information in the areas of biology, genetics and medicine’.

In a letter addressed to the Prime Minister of Japan last May, Mr Koïchiro Matsuura, Director-General of UNESCO, requested that the G-8 adopt a declaration reasserting the principle of guaranteeing the global scientific community **free access to data derived from human genome sequencing**, in the interests of humanity as a whole. The Okinawa Communiqué (23 July 2000) thus states, in paragraph 62:

‘We consider this mapping to be critically important for all humanity and call for the further rapid release of all raw fundamental data on human DNA sequences as such. We also emphasise the importance of pursuing the post genome-sequence research on the basis of multilateral collaboration.’

The Universal Declaration on the Human Genome and Human Rights is not a binding instrument, but to quote Mr Mohammed Bedjaoui:

‘The formal adoption of a declaration on the protection of the human genome can only be the starting point for an in-depth study, followed by effective practical measures worldwide to ensure that this heritage is respected in all circumstances and transmitted intact to future generations.’<sup>9</sup>

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9. Speech given at the closing of the 2nd session of UNESCO’s International Bioethics Committee (September 22, 1994).

## B. REGIONAL ORGANIZATIONS

### 1) The European Patent Office (EPO)

Twenty States, including the fifteen EU Member States, are parties to **the European Patent Convention**, which entered into force in 1973. The European Patent Office, based in Munich (Germany), is in charge of implementation. It grants patents in accordance with Convention provisions, and since the 1970s has been in charge of the patent system in Europe. Theoretically, this system is totally independent from the European Union. But ever since it failed in its attempt to create a community-wide patent - and pending a forthcoming renewed attempt so to do - the European Union has largely relied on the Munich system.

Furthermore, the European Patent Office, three quarters of the members of which are member of the EU, has already started applying the criteria defined by Community Directive 98/44/CE on the legal protection of biotechnological inventions. This approach, which has led to the granting of a number of patents on human genes, is illegal insofar as it imposes on Member States rules, which have not yet been adopted by their domestic law. In addition, non-EU Member States are thus made to abide by rules totally foreign to their legal systems as well as to what may be their political will.

#### Exceptions to Patentability

The Office's policy with respect to the patentability of living organisms has undergone a number of radical changes, no doubt because of the difficulties involved in accommodating new demands linked to biotechnological progress and the exceptions to patentability provided for in the Convention. **Article 53** of the Convention rules out the patentability of 'plant or animal varieties', as well as 'inventions the publication or exploitation of which would be contrary to 'ordre public' or morality'.<sup>10</sup> The Convention does not explicitly address the issue of human beings, which leaves the Office with some leeway in interpreting its provisions, and in particular those relative to 'ordre public'.

According to **Article 52 § 4**, methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are not patentable. Conversely, 'this provision shall not apply to products, in particular substances or compositions, for use in any of these methods'.

#### The European Patent Office's policy and the challenging of its decisions

In 1992, the Office undertook to grant a patent to the Du Pont corporation for the cancer-developing **Onco mouse**, without any legal grounding, and without opening discussions on the possibility of revising the Convention. The patent in question covers not only the genetic engineering process leading to this type of mouse, but the mouse itself, as well as all drugs that could be developed with the aid of said mouse. Its extension is thus potentially unlimited.

In 1995, Greenpeace filed a challenge, and ultimately won a case against a patent granted to Belgian company PGS (Plant Genetic System), for a plant with resistance to a number of herbicides. The arguments used in this case were based on the idea that living organisms cannot be considered as inventions, and this led the Board of Appeals to rule that **transgenic plants and their seeds cannot be patented**. This remained the prevalent policy until 1998, i.e. more or less until the Community's Directive was passed. Subsequently the Office once again started granting patents for plants and parts of the human body. Greenpeace

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10. In the framework of the current revision process, this last exclusion is in the process of being replaced by the expression 'the commercial exploitation of which would be contrary...' (which is reminiscent of Directive 98/44/CE).

has filed a challenge against a patent granted to Biocyte for umbilical cord blood (EP 0343 217).

This same NGO discovered last October a patent application filed with the European Patent Office by Stem Cell Sciences (Australia) and Biotransplant (USA), for the cloning of embryos, including human embryos, as well as mixed species embryos from pigs and humans (WO/99/21415). These companies acknowledged having already produced mixed pig and human embryos by inserting a human embryo nucleus into pig cells. In addition the companies applied for an exclusive right to genetic manipulation of embryos produced with their technology. No specific medical reason was invoked. The companies simply wished to demonstrate the feasibility of this transfer and wanted to get a very broad patent for the technology. Greenpeace revealed the existence of this patent and filed a challenge with the Patent Office. Five days later, bowing to media-conveyed outrage, the two companies withdrew their patents and declared they would never again include human embryos in their patent applications. Greenpeace claims that as long as the law allows human gene patenting, as is the case today, the European Patent Office will continue granting patents on everything that is not explicitly excluded. The incorporation of the EU Directive into the Munich Convention may prove to be very dangerous<sup>11</sup>.

The Diplomatic Conference for the Revision of the European Patent Convention, which took place in Munich, November 20-29, 2000, did not address the patentability of biotechnological inventions. According to the States Parties to the Convention, and in view of the current EU Directive on biotechnology<sup>12</sup>, and the conformity of the EPC with its provisions, no initiative seems to be called for as yet<sup>12</sup>.

Previously, a number of States party to the Convention had however suggested adopting a supplementary protocol to specify criteria to be used nationally for the application of the morality exclusion in the fields of human and animal tissue. The Nuffield Council on Bioethics recommended that the UK government support this initiative.<sup>13</sup>

## 2) The European Union (EU)

### DIRECTIVE 98/44/CE

A draft European Directive was first presented by the Commission in 1988. Nearly seven years later, the European Parliament finally decided to reject the text, mainly because the directive provided for the patentability of genes as such, be they of plant, animal, or human origin. A few months later, the Commission tabled a new proposal, including a number of modifications which did not however introduce significant changes of substance. Two amendments submitted by the Greens, on the issues of bio-piracy and donor consent, were thrown out by the Commission, thus imposing a stricter majority rule for the adoption of the two amendments (ie a majority of MPs, as opposed to a majority of votes cast). The amendments did not garner this majority, and directive 98/44/CE relative to the legal protection of biotechnological inventions was therefore passed unamended, and adopted by the Union's Council on July 6, 1998.

### The patentability of human genes in Directive 98/44/CE

Paragraph 1 of Article 5 of the Directive states that:

‘The human body ... and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.’

11. Greenpeace, press release, ‘Two biotech companies withdraw embryo patents’, October 10, 2000.

12. European Patent Office, Press Release 5/00 ‘Opening of the Diplomatic Conference for the Revision of the European Patent Convention’, November 20, 2000.

13. ‘Human tissues: ethical and legal issues’, April 1995, § 11.43 and 13.43.

The French National Academy of Medicine, in a recent report<sup>14</sup>, has underscored the validity of this paragraph's reasoning. Whereas French Law 94-653 grounds the non-patentability of the human body in purely ethical reasons, the directive adds to that a number of legal arguments insofar as it states that elements of the human body, which pre-exist in nature, are only revealed following a discovery, as opposed to an invention, and are as such not patentable.

The contradiction appears in the following segment of §2:

'An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.'

This assertion contradicts the principle of patent law according to which natural elements are not patentable because they do not involve an inventive step: asserting that isolating a gene can be tantamount to inventing it is debatable. Furthermore, this goes against the ethical principle of respect for human dignity, and its consequence, the principle of non-commercialization of the human body. It also goes against the definition of the human genome as 'heritage of humanity', as proclaimed by the international community in the Universal Declaration on the Human Genome and Human Rights.

The Directive justifies this stance by stating that 'whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself' (Whereases, §21). But is such is the case, shouldn't the patent apply to the process, rather than to the product?

### **The Directive's most controversial points**

- the distinction between discovery and invention is done away with: § 2 contradicts § 1 insofar as it considers genes to be inventions on the sole grounds that they have been isolated or produced using a technical process. The Directive confirms this misreading of the distinction between discovery and invention when it states, in Article 3 §2 that:

'Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature'

or again, in paragraph 20 of the preamble, that,

'whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process (...) is not excluded from patentability, even where the structure of that element is identical to that of a natural element...'

- the distinction between product patent and process patent is not abided by: the Directive extends the effects of a process patent to a product patent. It thus confers to patents covering processes used to identify, purify, classify or reproduce outside the human body (§21, preamble) the effects of product patents. Patents not only cover the process by which genes are isolated and reproduced, but also the gene itself and all its possible uses: all in all they grant exclusive rights to produce, import and market the gene.

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14. Bureau C., 'a propos de la brevetabilité des gènes', Groupe Science (Académie des Sciences, Académie des sciences morales et politiques, Académie nationale de médecine), Bulletin de l'Académie nationale de médecine, 2000, tome 184, n°5, pp. 1069-1073.



- the adoption of an approach according to which human beings are reduced to an assembly of cells and DNA sequences: this commercial view of the human body and its elements, considered as spare parts, goes against a view of man based on the dignity of unique, free, and autonomous human beings.
- the rejection of a consent provision: Parliament had adopted an Article 8bis that demanded that proof be provided that biological material covered by patents had indeed been taken in accordance with applicable national law, as well as with the explicit consent of donors, in the case of human biological material. This ethical clause was rejected by the Commission, which simply inserted it in the Preamble (n°26).
- the condition of strict reproducibility of invention results has been eliminated: One of the fundamental conditions to be met in order to obtain a patent was that the invention give rise to identical results when reproduced. This condition has been eliminated in the Directive - an understandable development given that it is not yet possible to obtain genetically identical copies of living organisms. The Directive circumvents this obstacle by simply requiring that a copy of the invention be deposited (art. 13)<sup>15</sup>.
- disclosure of the industrial application of genes and extension of protection conferred: article 5.3 requires that the industrial application of a sequence or a partial sequence of a gene be disclosed in the patent application. Requiring disclosure of this type is not the same as requiring a demonstration through experimental evidence<sup>16</sup>. In practice, function is simply deduced by companies on the basis of computerized comparisons, and industrial function is then concretely presented, whereas in actual fact it is only induced. By way of illustration, HGS patented gene CCR5. Years later, scientists discovered that this gene plays a crucial role in the intracellular penetration of the HIV virus. All therapeutic developments based on this gene will however be dependent on the HGS patent, as the company may oppose the use of the sequence, or require the payment of a fee.

### **Scope of Protection - Directive 98/44/CE**

#### **Article 8**

1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

### **Exclusions from the scope of patentability: ‘ordre public’, cloning processes and therapy**

Article 6 of the Directive echoes the 1973 European Convention ban on patenting inventions the exploitation of which would be contrary to ‘ordre public’ or morality, as exploitation cannot be so qualified on the sole grounds that it is prohibited by laws or regulations. Article 6 goes on to state that the following, in particular, are to be considered unpatentable:

15. Paul Lannoye, Green MEP, ‘Directive européenne sur le brevetage du vivant’, OGM Danger, [www.altern.org/ogm](http://www.altern.org/ogm).

16. Sureau C., ‘A propos de la brevetabilité des gènes’, op. cit., p. 1072.

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

Conversely, Preamble § 42, all but unnoticed, limits the scope of application of 6c), insofar as it states that ‘in any case such exclusion does not affect inventions for therapeutic or diagnostic purposes, which are applied to the human embryo and are useful to it’.

As regards therapeutic and diagnostic techniques, Preamble § 35 states, in accordance with the European Patent Convention and the TRIPS Agreement, that:

Whereas this Directive shall be without prejudice to the provisions of national patent law whereby **processes for treatment** of the human or animal body **by surgery or therapy** and **diagnostic methods** practised on the human or animal body are **excluded from patentability**.

By referring to provisions of national patent law, this provision does not itself exclude such therapies from the scope of patentability: national legislation in any Member State authorizing the patenting of such therapies would not go against the Directive. In any event, Mr Lannoye, MEP for the Green Party rightly notes that ‘if human cells or genes are patentable, their possible therapeutic uses are also patent-protected’. An example: Biocyte was granted European patent FP343.217 for human blood cells taken from the umbilical cord; the patent covers both the blood cells and their possible therapeutic uses. Many scientists and clinicians have opposed this state of play:

- clinicians are opposed because they feel that Biocyte will thus be in a position to control all future uses of such cells and to threaten patients’ interests by requiring the payment of fees. The resulting price hike is likely to introduce segregation between the rich and the poor;
- scientists are opposed because they will no longer have free access to cells the features of which hold much promise for future medical research.

### Transposing the Directive

The Directive has been much criticized among NGOs, including Greenpeace, and professional associations, such as the International Society of Bioethics who recently stated that ‘the human genome is the heritage all humanity. It is not per se patentable’<sup>17</sup>. What is however more concerning still is the criticism the Directive has elicited on the part of European Union Member States<sup>18</sup>.

On October 19, 1998, the **Netherlands**, supported by **Italy** and **Norway** (who, as a Member of the European Economic Area has stated it did not intend to apply the Directive) filed an appeal with the European Communities’ Court of Justice against the Directive, on the following grounds:

- the Directive is incompatible with the Convention on Biological Diversity, which only authorizes the use of genetic resources when the peoples’ concerned have given their informed consent;

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17. Bioethics Declaration of Gijon, June 2000, adopted at the close of the World Congress on Bioethics (Gijon, Spain, 20-24 June 2000).

18. In Thomas Schweiger and GRAIN, ‘The directive that just won’t lie still’, *Seedling*, September 2000.

- although it claims solely to harmonize Member States' legislation, the Directive goes much further, and is actually stating new rules. And in order to be passed, all new rules require unanimity, as opposed to special majorities;
- far from respecting the European Patent Convention, the Directive in fact attempts to modify it, whereas the Convention's membership includes countries which are not members of the European Union.

By a ruling handed down on July 25, 2000, the Court refused to grant a stay of execution to the appealing parties, which would have suspended the application of the Directive pending a decision being reached as to substance, i.e. as to the nulling of the Directive.

**France** asked the CCNE (*Comité consultatif national d'éthique*) for its opinion, which was published on June 8, 2000. The CCNE advised the government not to transpose the Directive without introducing modifications of substance. French authorities have since then declared that they did not intend to transpose the Directive pending substantive modifications being renegotiated at the European level. They have asked Mr Romano Prodi, President of the Commission, to open re-negotiations.

**Belgium** is also experiencing difficulties in implementing the Directive. It has posted its draft transposition bill on its web site, inviting comments from visitors. This draft differs from the Directive on the definition of inventions. The Belgian Consultative Committee on Bioethics feels that 'the draft bill in its current form calls for serious adaptation'<sup>19</sup>. The Committee has in particular stressed:

- the need to guarantee the principle of voluntary informed **consent**, and underscored the fact that 'this information shall include, if appropriate, indications as to possible industrial or commercial uses of the results of experimentation'.
- the fact that Directive Article 5 § 1 should be supplemented with an explicit reference to the **non-commercial nature** of the human body.
- the fact that intellectual property must be the object of **non-extensive protection**: 'at the very least, patent protection should not be extended to the simple knowledge of this (genetic) information, and by the same token, to all possible future - and for the nonce ill-defined - applications which might be derived from said knowledge'.

**Germany** has adopted a draft bill which also includes differences, in particular a reference to German law regarding human embryos, which is very un-permissive. The government has also stated that the Directive was not adequate and that the negotiation process should be started anew.

As for **Denmark**, the government's Consultative Committee on Ethical Issues recommended, in an opinion published in May 2000, that the Directive not be transposed into national law, as it views the patenting of human genes as unethical and has underscored the negative repercussions this may have for medical patients. The Danish Parliament did however very narrowly pass the transposition.

**Finland, Ireland, and the United Kingdom** have transposed the Directive. **Luxembourg** is in the process of reviewing a law identical to the Directive. **Spain** has submitted a draft transposition bill to the European Commission, which considered it to be inappropriate and sent it back. In **Greece**, the transposition process is very lengthy, and the

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19. Opinion n° 12, 10 January 2000, regarding the legal protection of biotechnological inventions, and reference to Opinion n°4, 9 February 1998, regarding the protection of biotechnological inventions.

draft is still being examined at ministerial level. Finally, in **Sweden**, discussions are only due to begin next year.

Criticism has also been expressed extensively at the international level, in both intergovernmental and non-governmental circles. Thus the **Council of Europe** has invited European Union Member States to request the re-negotiation of Directive 98/44/CE, and has expressed approval of the appeal filed by the Netherlands, and supported by Italy.<sup>20</sup> Many NGOs, such as Greenpeace, GRAIN<sup>21</sup> and RAFI<sup>22</sup>, have asked that the Directive be modified so as to rule out the patentability of living organisms.

## THE DRAFT EUROPEAN CHARTER

A draft European Charter has been adopted by the EU's political bodies but as it has not been incorporated into treaties, it is not yet part of Community law. This Charter contains a provision relative to bioethics. Article 3§2 states that 'in the fields of medicine and biology, the following must be respected in particular:

- the free and informed consent of the person concerned, according to the procedures laid down by law; (...)
- the prohibition on making the human body and its parts as such a source of financial gain; (...)'.

This provision is fairly general and does not mention the issue of patenting. All will depend on how the expression 'as such' is interpreted and used. No doubt interpretations consistent with Directive 98/44/CE will view body parts as they view genes and consider that when such body parts are isolated from the body, they are no longer to be considered as 'body parts as such'.

## OPINION OF THE EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES (EGE)

In April 1996, the Commission requested the opinion of its Group of Advisers on the Ethical Implications of Biotechnologies (which was replaced in 1998 by the European Group on Ethics in Science and New Technologies), on 'patenting inventions involving elements of human origin'. The Group of Advisers, in its opinion, stressed the ethical principles of **non-commercialization of the human body** and of free and informed **consent** on the part of the 'person from whom retrievals are performed', and on the basis of which the invention will be developed. At the same time, the Group **did not rule out the patentability** of inventions based on the knowledge of a gene or a partial human gene sequence, provided a sufficiently specific and identified industrial application could be demonstrated.

Excerpts of Opinion n°8 on the ethical aspects of patenting inventions involving elements of human origin:

- [...] the simple knowledge of the complete or partial structure of a gene cannot be patented [...];
- [according to the] usual conditions of patentability [but also] according to the ethical principle of non-commercialization of the human body [...] no patent can be given on the human body or on its elements [...];
- [no] remuneration to the person from whom the samples are retrieved can be allocated [...];

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20. Recommendation 1468, 2000, 'Biotechnologies'.

21. Genetic Resources Action International, Barcelona, Spain.

22. Rural Advancement Foundation International, Canada/United States of America.

- an invention based on the use of elements of human origin, having been retrieved without respecting the principle of consent will not fulfill the ethical requirements [...];
- concerning the inventions issued from the knowledge of a human gene or a partial human gene sequence, the granting of a patent is acceptable only if, on the one hand, the identification of the function [...] allows new possibilities [...] and , on the other hand, if the intended use of the patent is sufficiently specific and identified.

Professor Dietmar Mieth, member of the Group of Advisers, added a remark of considerable interest. He stated his support of the Group's Opinion, but felt that 2.5 should be supplemented as follows:

'The patent shall not protect the **gene per se**, but the **specific and identified use** thereof.'

This is one of the most controversial issues in this debate, but the Group as such did not support this position, which may appear far more acceptable from an ethical standpoint.

### 3) The Council of Europe

The Council of Europe is at the origin of the first international convention in the field of bioethics, which was adopted in a regional context. **Article 21** of this convention prohibits financial gain derived from the human body, and states:

The human body and its parts shall not, as such, give rise to financial gain.

The explanatory report states that, under this provision, organs and tissues proper, including blood, should not be bought or sold or give rise to financial gain for the person from whom they have been removed or for a third party, whether an individual or a corporate entity such as, for example, a hospital. Under this article, patenting blood cells taken from an umbilical cord is not authorized.

However, technical acts (sampling, testing, pasteurisation, fractionation, purification, storage, culture, transport, etc.) which are performed on the basis of these items may legitimately give rise to reasonable remuneration. For instance, this Article does not prohibit the sale of a medical device incorporating human tissue which has been subjected to a manufacturing process as long as the tissue is not sold as such. Further, this Article does not prevent a person from whom an organ or tissue has been taken from receiving compensation which, while not constituting remuneration, compensates that person equitably for expenses incurred or loss of income (for example as a result of hospitalization).

The question of patents for biotechnological inventions was not considered in connection with this provision. The Council of Europe felt that the complexity of the problem of patents was such that a detailed study was necessary before any regulations were drawn up: 'if such a study led to the conclusion that regulations on the subject were desirable, the regulations should include principles and rules suited to the specific nature of the subject'.

The **Parliamentary Assembly** of the Council of Europe has for its part, taken the issue up in a series of recommendations:

- **Recommendation 1240** (1994) on the protection and patentability of material of human origin;
- **Recommendation 1425** (1999), on biotechnology and intellectual property;
- **Recommendation 1468** (2000), on biotechnology, which endorses the conclusions of the 'Biotechnologies' report submitted on 5 June 2000 by Mr J.-F. Mattei, rapporteur of the Committee on science and technology.

- **Recommendation 1512** (2001), on the protection of the human genome by the Council of Europe

The main issues raised by these recommendations are the following.

- **Recommendation 1240** (1994):

- Human beings are subjects - not objects - of law, the human body is inviolable and inalienable by virtue of its relationship to a person endowed with rights, and limits must therefore be set to how it is used.
- There is a need to protect equipment, methods, and products connected to biotechnological research
- The **European Patent Convention** contains provisions which are today inadequate, and the European Patent Office is addressing these issues in an environment where patenting is the norm and commercial considerations are omnipresent.
- The Assembly recommends that the Committee of Ministers initiate the immediate preparation of a protocol to the draft convention, setting limits to the application of genetic manipulation to human beings.
- Calls for the European Patent Office to transmit to the Council of Europe an annual report on decisions on applications for patents relating to living material.

- **Recommendation 1425** (1999):

- Research units should conform with the **Convention on Biological Diversity**, guaranteeing both the principle of free scientific access to worldwide genetic resources and the interests of developing countries in sharing the benefits of technological progress.
- For ethical reasons there are also severe reservations against patenting living organisms.
- The issue of patenting living organisms should comply with the provisions of the CBD, and greater account should be taken of the **interests of developing countries** in WTO's **TRIPS Agreement**; WTO should comply with the CBD.
- Monopolies granted by patent authorities may undermine the value of regional and worldwide genetic resources and of traditional knowledge in those countries that provide access to these resources.
- The aim of sharing the benefits arising from the utilization of genetic resource does not necessarily require patent-holding but requires a balanced system for protecting both intellectual property and the 'common heritage of humankind'.
- Neither plant-, animal- nor human-derived genes, cells, tissues or organs can be considered as inventions, nor be subject to monopolies granted by patents.
- The Assembly recommends that the Committee of Ministers, in cooperation with a number of international organizations, including UNESCO,
  1. improve international legislation in this field, by studying in detail all aspects linked to the protection of intellectual property in biotechnological innovations;
  2. develop a code of conduct for scientists which guarantees free access to genetic resources and benefit-sharing;
  3. discuss a suitable alternative system to protect intellectual property.

- **Recommendation 1468 (June 29, 2000):**

- the Assembly recommends that the Committee of Ministers:
  1. promote the adoption of the precautionary principle as a common tenet of decision-making, once its scope has been clearly defined. The Assembly welcomes the fact that in January 2000 this principle was for the first time included in an internationally adopted protocol to the CBD on biosafety.
  2. Introduce a bioethical labeling procedure for new technologies, which would take into account a number of basic ethical principles, including the non-commercialization of the human body<sup>23</sup>.
  3. Convene a group of experts to elaborate a future international convention on the use of living matter on a worldwide basis, under the auspices of organizations which are able to assume the responsibilities that go along with overseeing such a convention.
  4. Call on the member states of the European Union to request the re-negotiation of Directive 98/44/CE of 6 July 1998, and express support to the Netherlands and Italy in their appeals before the Court of Justice of the European Communities.

- **Recommendation 1512 (2001):**

Concerning the Human Genome Project, the Assembly:

- is of the opinion that the results of this grandiose research effort – in which the United States has the lead over Europe – must be made available to all, genetic information being a common human heritage, as set out in Article 1 of the Universal Declaration on the Human Genome and Human Rights, adopted at Unesco in Paris on 11 November 1997.
- recommends that member states set up a body or authority to fulfill on a permanent basis the task of monitoring the development of the Human Genome Project research process, ensuring respect for ethical principles in the context of research on the human genome, assessing the effects of such research also regarding health risks, and giving thorough consideration to all ethical aspects of the project ;
- ask all Council of Europe member states to strive to change the basis of patent law in international fora, as far as the ownership of human being tissue and genes is concerned, into law pertaining to the common heritage of mankind.

#### **4) The Organization of African Unity (OAU)**

Following commitments undertaken in the framework of the TRIPS agreement and, more generally, with a view to combating the exploitation of African countries' genetic resources by more developed countries, the Organization of African Unity (OAU), which groups 53 States, has adopted a 'model law' that aims to be an alternative solution to the generalized adoption of the intellectual property rights approach. Developed by the Science, Technology, and Research Committee of OAU, this framework-law is based on the Convention on Biological Diversity, and endorses a number of its fundamental principles: state sovereignty over resources, need for prior consent on the part of those populations concerned, and equitable sharing of benefits derived from the commercial utilization of such resources.

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23. For more information on this bioethical labeling proposal, see § 44-47 of the 'Biotechnologies' report, 5 May 2000, Doc. 8738, filed by Rapporteur J.-F. Mattei.

Africa has thus shown its will to play a leading role in thinking about the uses of living organisms. Although the law does not explicitly focus on the human genome, but rather on all living organisms, and more specifically on animals and on plants, it does offer an alternative legal model to the typically western intellectual property rights approach. It offers another way of reconciling inventors' commercial interests and the respect for natural genetic resources. This model law on 'community rights and the control of access to biological resources' specifies the following conditions of access:

- prior informed consent of both the State and the indigenous and local communities;
- issuance of written authorizations by the relevant national authorities;
- determination by these same authorities of the amount of fees payable for the authorization to exploit, fees being determined on the basis of sales of exploited resources;
- implementation of mechanisms to ensure the fair and equitable sharing of benefits deriving from the commercial utilization of such resources, in particular through the payment of fees levied into a special fund for the financing of projects defined by local communities with a view to the sustainable development, conservation, and use of genetic resources.

### The Model Law and WTO

The model law further defines a system to protect the intellectual property rights of the inventors of plant varieties, in response to Article 27 §3b of the TRIPS agreement, which states that 'Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof'. The *sui generis* system defined by the OAU is far less protective than is the patent system. Contrary to the patent system, it acknowledges:

- **an exemption for research:** protected 'varieties' may be used without constraints and free of charge as a genetic resource by scientists or research workers attempting to create new 'varieties';
- **farmers' privileges:** farmers shall be allowed to retain part of their harvest in order to replant it the following year without having to pay a fee.

It remains to be seen whether WTO shall consider this system to be 'effective' under Article 27 § 3b. The African Group not only wished to have the WTO evolve towards its model law, but it also intends to request that a **general ban on the patenting of living organisms** be introduced into the TRIPS agreement. As stated by Kenya in a communication to the WTO on behalf of the African Group<sup>24</sup>, «there is no scientific basis for the distinction made between plants and animals (which may be excluded) and micro-organisms (which may not be excluded)». The same applies for the distinction between 'essentially biological' processes and microbiological processes. Consequently, the African Group requested that the review process clarify that all living organisms without distinction cannot be patented, and that the same apply to all natural processes that produce these living organisms.

The United States of America is very hostile to this proposal as its own goal - the elimination of all possible exclusions of living organisms from the scope of patentability - is the complete opposite of that stated by the African Group.

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24. 6 August 1999, 'The TRIPS agreement', WT/GC/W/302.



## 5) The Eurasian Patent Organization (EAPO)

The Eurasian Patent Organization was set up on September 9, 1994, in Moscow, on the occasion of the signing of the **Eurasian Patent Convention**. This Organization is the successor to the single patent space that existed, under the Soviet Union, over the corresponding territory. The Member States, ten in all including the Russian Federation, have thus reiterated their desire to cooperate. The Eurasian Patent Convention entered into force on August 25, 1995.

**Rule 3(1) of the Patent Regulations** under the **Eurasian Patent Convention** states that a Eurasian patent shall be granted for any invention that is new, involves an inventive step, and is industrially applicable. **Paragraph (5)** of Rule 3 provides for exclusions from the scope of patentability for:

- plant varieties and animal breeds;
- solutions that are contrary to public order or morality.

Paragraph 2, however, states that the subject matter of an invention may be a device, a process, a substance, a micro-organism strain, a plant or animal cell line, or the use of a device, process, substance, strain or line. The Regulations therefore explicitly authorize the patenting of plant and animal cell lines, without stating any specific exception for human beings. It therefore appears that the patenting of human genes is not likely to come up against significant obstacles under this regime, unless such patenting is considered to be contrary to public order or morality. As is always the case when legislation is insufficiently precise, all will depend on interpretation.

## *Part Two - National Regulations*

On 14 March 2000, United States of America President Bill Clinton and United Kingdom Prime Minister Tony Blair published a joint statement expressing their conviction that data derived from human genome sequencing should be made freely accessible to the global scientific community and that discoveries made possible by human genome sequencing should be used to benefit human health. As underscored by Mr Koïchiro Matsuura, Director-General of UNESCO, this statement invokes the very principles set out in the Universal Declaration on the Human Genome and Human Rights.

It does not however necessarily correspond to reality, especially in the United States of America, where the patenting of human genes is the rule. Within the international community, the range of solutions adopted is quite broad.

### **A. States least favorable to human genome patentability**

#### **Austria**

Austrian patent law echoes a number of provisions stated in the European Patent Convention, and the Austrian Patent Office has taken on board criteria adopted by the European Patent Office. Austria, contrary to other countries parties to the Convention, provides for a ban on the patentability of human organs and products derived from the human body (cell lines, genes, and DNA sequences).

#### **Czech Republic**

Human tissue and genes: the protection of biotechnological inventions is regulated by Law 527/1990. Human beings, their organs, as well as **all elements derived therefrom, such as cell lines, genes, and DNA sequences, are excluded from patentability**. The same applies to plants and animals as well.

Methods for surgery, therapy and diagnosis (including stem cell therapy): on the basis of Section 4b of this same law, all such methods applied to humans and animals are excluded from patentability.

The Czech Republic aims to adapt its legislation to European standards, with a view to its joining the European Union.

#### **Finland**

Human tissue and genes: according to Chapter 1, Section 1 of the **Patent Act**, human beings and human organs cannot be patented. Human beings cannot be part of industrial processes and patents must not be granted for inventions the exploitation of which is contrary to morality. Under this same Section 1 products derived from the human body, including cell lines, genes, and DNA sequences can be patented. Finland however points out that such inventions may be contrary to morality if the product involved has been taken from a human embryo, and if the only way the invention can be obtained involves using human embryos<sup>25</sup>.

Methods for surgery, therapy and diagnosis (including stem cell therapy): methods for the therapy and diagnosis of animals and human beings cannot be patented. Gene therapy is

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25. Finland's reply to the OECD questionnaire on intellectual property rights in the field of biotechnology, February 1999, OECD.

considered as a therapy, whereas biopharmaceutical products can be considered on par with pharmaceutical products and therefore deemed patentable, as can genetically modified cells, produced via gene therapy technology.

Genetic engineering methods applied to human beings for purposes other than therapy or diagnosis are not patentable because they are contrary to morality. In Finland, no such patent applications have been filed.

## France

Currently, issues of human genome patentability are covered by **Article 611-17 of the Intellectual Property Code** which was modified in 1994 on the occasion of the adoption of the so-called 'bioethics' laws, with a view expressly to rule out the patentability of the human body, its elements and its products.

Article 611-17 reads as follows:

'The human body, its elements and its products cannot as such be the object of patents, nor can knowledge relative to the total or partial structure of human genes.'

The draft bill aiming to transpose Directive 98/44/CE into the French intellectual property code was to replace this text with provisions quasi-identical to those contained in the Community Directive. The *Comité consultatif national d'éthique* (CCNE) published an opinion on this draft bill on June 8, 2000. It concluded that such a development should not be passed without there being a democratic debate involving people beyond the borders of the scientific community and indeed, those of the country as such. Pending such a debate, the CCNE did not see any reason to move away from the principles which presided over the drafting of the July 29 1994 legislation, and emphasized that 'the knowledge of a gene sequence can under no circumstances be considered tantamount to an invented product, and is therefore not patentable'. France intends to abide by this opinion and has requested a renegotiation of the directive on biotechnological inventions.

## B. The most common intermediate stances

### Belgium

Belgian patent law dated March 28 1984 echoes provisions contained in the European Patent Convention. It therefore contains no explicit exclusion concerning human beings. Belgium has no case law in this regard. A draft bill aiming to transpose the Community Directive into national legislation is in the process of being reviewed. The Consultative Committee on Bioethics has expressed an unfavorable opinion regarding the transposition of the Directive and has stressed the significance of introducing into this text principles of consent, non-commercialization of the human body, and non-extensive patent protection (cf. section on the European Union).

### Canada

Human tissue and genes: neither human beings nor their organs are patentable, but products derived from the human body, including cell lines, genes, and DNA sequences, are.

Methods for surgery, therapy and diagnosis (including stem cell therapy): such methods are excluded from patentability, with the exception of diagnostic methods, provided they imply neither surgery nor therapy. Biopharmaceutical products obtained via gene therapy are patentable. There have been no court rulings in this field.

As regards consent to the use of excess tissue, **Article 22 of Quebec's new Civil Code**, adopted in December 1991, states that no part of the human body (organ, tissue or

other substances) taken from a person in the framework of therapy administered to said person may be used for research without the consent of said person or a person authorized to act on their behalf. According to the National Council on Ethics in Human Research (NCEHR), it remains to be seen whether this new provision will be interpreted in a way that would rule out anonymous and independent studies on excess tissue, without consent.

## Italy

Italy has prepared a **draft transposition bill** for Directive 98.44/CE, which reproduces the rules set forth in the Community text, but adds a provision requiring the voluntary and informed consent of those from whom genetic material is taken for the purposes of the patent. However, on February 25, 2000 the National Bioethics Committee published an opinion concerning the patentability of cells taken from human embryos.

This opinion firstly underscored the ‘extreme seriousness’ of the decision reached by the European Patent Office to grant the University of Edinburgh and Biotransplant a patent that provides for the isolation and culture of adult and embryonic stem cells, as well as for their genetic modification. The correction subsequently published by the Office, according to which the patent does not cover the human species nor therefore human cloning, has no legal value insofar as it does not introduce any changes into a text which is extremely explicit: ‘all animal cells, especially mammalian species, including human cells’ (§ 0011 of patent EP 695 351). This patent, concluded the NBC, is therefore still legally valid in its current form, and in the practical consequences that may stem therefrom. The NBC furthermore expressed satisfaction at the appeals Italy intended to file against the granting of this patent.

As regards the European Directive, the NBC has restated its opposition to the patentability of human beings and suggested that in the course of transposing the Directive into national law, an interpretation be defined that would rule out all ambiguity regarding the **illicit character of human being patentability**.

## Republic of Korea

Human tissue and genes: neither human beings nor their organs can be patented. Products derived from the human body (cell lines, genes and DNA sequences) can however be patented. No provision in patent law precludes the patentability of animals as such. Korean legislation also takes into consideration the ways in which products are obtained: products which can only be obtained via methods requiring the use of the human body or its parts (through bioreactors, for instance) cannot be patented.

Methods for surgery, therapy and diagnosis (including stem cell therapy): such methods can be patented only insofar as they apply to animals, but not for human applications. Therapeutic methods used to treat human beings are considered as not having industrial application. Products obtained via gene therapy technology are patentable if their obtention process does not involve the human body.

Public order, morality and public health provide grounds for exclusion.

## Switzerland

Switzerland is a member of the European Patent Organization. Most patent applications for biotechnology are filed with the European Office rather than with the Federal Intellectual Property Institute.

Human tissue and genes: human beings are not patentable, whereas derived products of human origin, including elements isolated from the human body or otherwise produced using technological processes may constitute patentable inventions.

Methods for surgery, therapy and diagnosis (including stem cell therapy): methods for surgery, therapy and diagnosis applied to the human or animal body are not patentable. Methods involving the genetic modification of humans are prohibited by the Swiss Constitution (Article 24 *novies*). As for methods involving the genetic modification of animals, they are not excluded a priori.

## Taiwan

Patent law from May 29 1944 was amended in May 1997 to take into account TRIPS agreement requirements. Article 21 bans patentability for:

1. New varieties of plants and animals, excepting technology for the culture or growing of new plant varieties;
2. Methods for surgery, therapy, and diagnosis of diseases affecting humans or animals;
3. Scientific theories and mathematical formulae;
- (...)
6. Inventions contrary to ordre public, morality, and health.

Taiwan has also had to introduce a principle stating the ban on producing, selling, or using patented products without patent-holder consent (Article 56). This law nevertheless contains a number of additional and original principles:

- Article 57 states that the effects of an invention patent right shall not extend to a number of specific circumstances:
  - where the invention is put into practice for research, educational or experimental purposes which involve no profit-seeking acts;
  - where the invention has been used in the country, except where knowledge of the manufacturing method was obtained by the applicant within six months prior to applying for patent.

## United Kingdom

Human tissue and genes: legislation makes no explicit reference to the patentability of human beings or their organs, but this is excluded on the grounds that it is contrary to morality and does not have industrial application. Derived elements, such as cell lines, genes, and DNA sequences are patentable. Animals are patentable as well.

Methods for surgery, therapy and diagnosis (including stem cell therapy): such methods are explicitly excluded from the scope of patentability when applied to humans or to animals, because of their lack of industrial applicability. Genetic engineering technology applied to humans or to animals for purposes other than therapeutic or diagnostic is conversely patentable.

## C. States most favorable to genome patentability

### Australia

Human tissue and genes: under Section 18, §2 of the Australian Patent Act, only human beings as such are excluded from patentability: human organs and derived products (cell lines, genes, and DNA sequences) are not covered by this exclusion. Animals per se, as well as their organs or animal varieties are not excluded either from patentability. The Patent Act considers that inventions are a manner of manufacture, which changes the form of a product. Thus, isolated and purified proteins are patentable. This principle is the same as that applied by the European Directive.

Methods for surgery, therapy and diagnosis (including stem cell therapy): the Australian Patent Act authorizes the patentability of methods for human and animal therapy and diagnosis, including gene therapy, both somatic and stem cell based, as well as genetic engineering methods applied to humans for purposes other than therapeutic or diagnostic (research, etc.) The only exclusion from patentability concerns essentially biological processes for the production of human beings (Section 18, §2, Australian Patent Act).

Finally, legislation does not provide for any exclusion based on ethical or moral grounds.

## Japan

Human tissue and genes: human beings cannot be patented. Human organs are not specifically excluded from patentability, but may fall under Section 32 of Japan's Patent Law, which bans patents for inventions which are contrary to ordre public or to morality. Products derived from the human body (cell lines, genes, and DNA sequences) are patentable.

Methods for surgery, therapy and diagnosis (including stem cell therapy): Section 29 §1 bans the patenting of such methods when they apply to human beings, but authorizes their patenting for animals. Genetic engineering methods are only patentable if they apply to animals.

The Japanese patent office is in favor of stronger intellectual property rights as applied to biotechnology. The office has voiced its opposition to the TRIPS agreement, which rules out the patentability of plants and animals, and, like the United States of America, has expressed the hope that this exclusion will be eliminated. Japan, where plants and animals are patentable, is equally opposed to the exclusions provided for under the Munich Convention. The office has further stated that it is aware of problems which may derive from human genome sequencing, as sequencing is only carried out in developed countries, while developing countries are concerned, *inter alia*, by their biodiversity, but its only suggestion has focused on harmonizing the way in which experimenting should be carried out in developed countries<sup>26</sup>.

## United States of America

In the United States of America invention patentability is determined by the United States Patent and Trademark Office (USPTO), within the Department of Commerce, in accordance with relevant regulations. Patents are regulated by US Code Title 35, dating back to 1952 and last amended in 1999 by the American Inventors Protection Act. Section 103 of Title 35 (35 U.S.C. 103) explicitly provides for the patentability of biotechnological processes<sup>27</sup>.

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26. Council for industrial property, International Affairs Division, Japanese Patent Office 'Towards the International Harmonization of Industrial Property Rights Systems in the 21st Century', 26 May 1999.

27. Section 103:

(b) (1) ... a **biotechnological process** using or resulting in a composition of matter that is novel under section 102 and non-obvious under subsection (a) of this section shall be considered non-obvious if :

(A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and

(B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.

(2) (...)

(3) For purposes of paragraph (1), the term '**biotechnological process**' means :

(A) a process of genetically altering or otherwise inducing a single - or multi-celled organism to :

(i) express an exogenous nucleotide sequence,

Prior to 1980, living organisms were considered to be part of nature and not patentable. US Supreme Court Ruling in *Diamond v. Chakrabarty*, 206USPQ 193 (1980) changed this interpretation insofar as it stated that micro-organisms produced using genetic engineering were not excluded from the scope of patentability as defined under Title 35, Section 101 of the Code, as they did not occur in nature. The first patent for a transgenic organism was thus granted.

In addition to criteria of ‘novelty’, ‘use’, and ‘non-obviousness’, the essential criterion establishing invention patentability is, according to the Court, the proof of ‘human intervention’ (or ‘manufacture’, in Section 101) on the matter to be patented, be it living or inanimate<sup>28</sup>.

The USPTO interpreted the Court ruling as follows:

- the Court did not want to limit its ruling to genetically modified living organisms;
- the Court opted for a very broad interpretation of the term ‘manufacture’ (section 101);
- the Court defined a number of elements in order to test patentability under section 101:
  - laws of nature, physical phenomena and abstract ideas are not patentable;
  - compositions or manufactures which do not occur in nature, are the products of human ingenuity, and have a name, a character and a specific use are patentable;
  - the development of useable products using raw materials prepared in such a manner as to give them new shapes, qualities, properties or combinations, be it by hand, or by machine is a ‘manufacture’ under section 101.

The USPTO’s policy is therefore tantamount to conferring very extensive protection, with exceptions granted only for ‘laws of nature, physical phenomena or abstract ideas’. No other exclusion, be it grounded in ordre public, public health, or ethical reasons is taken on board.

Human tissue and genes: the ruling handed down by the Patents Appeals Board on April 21 1987 (1077 OG 24) has nevertheless asserted that human beings cannot be patented under Section 101, as such patenting would be unconstitutional. Elements isolated from human bodies, including organs, as well as genes, DNA sequences and other elements can be patented.

### EST (Expressed Sequence Tags) and SNP (Single Nucleotide Polymorphism)

The USPTO has also granted patents for DNA fragments known as expressed sequence tags, because of their use as probes or checking elements. This elicited strong reaction on the part of a number of scientists, who criticized what they felt was the excessive ease with which the PTO granted patents, in this case on elements which can only be used as instruments. Such patents may seriously jeopardize the patenting of whole genes.

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(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

(iii) express a specific physiological characteristic not naturally associated with said organism;

(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody;

and

(C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

28. ‘The relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. Here, the respondent’s microorganism is the result of human ingenuity and research’.

In April 2000 HUGO (the Human Genome Organization) stated it opposed this type of patent. It equally opposes the patentability of **SNPs (Single Nucleotide Polymorphisms)**, which are variations in a gene sequence altering a single nucleotide. These elements do not meet the conditions of inventive step and use, as they are nothing but ‘pre-competitive information’, the function of which is not yet clear.

The patentability of these elements introduces obstacles into the very early stages of research. Furthermore, it may lead to situations where scientists wishing to use a gene will have to pay fees not only to individuals who have patented the whole gene, but also to all the holders of rights on the fragments making up said gene.

In June 1997, the Chairman of the National Academy of Sciences also voiced concern to the USPTO, in view of the Office’s granting of patents for DNA fragments, which are relatively easy to find, but are not very significant from a biological standpoint.<sup>29</sup> The Director of the NIH has also taken a similar position.

## **D. Developing countries and the quest for new rules**

### **The Andean Pact**

In 1996, Bolivia, Columbia, Ecuador, Peru and Venezuela adopted the Common System on Access to Genetic Resources (Decision 391).

This Common System defines access conditions to genetic resources, including derivatives of these resources. It states that access contracts must take into account **the rights and interests of the suppliers of genetic resources**, their derivatives and related intangible components<sup>30</sup>.

Intangible components are defined as any knowledge, innovation or practice (individual or collective) of actual or potential value associated with a biogenetic resource or derivative, whether or not it is protected by intellectual property rights. When resources include intangible components, decision 391 mandates:

- a) providing the identity of the supplier of said genetic resource and its derivatives, including their intangible components, and
- b) stating in an annex to the access contract what provisions have been taken to guarantee the equitable sharing of benefits deriving from access to the above-mentioned components.

### **Costa Rica**

The 1994 **Costa Rica Law on Biodiversity** defines a broad system for the protection of biological diversity covering not only the variability of living organisms, but also the intangible derived components embodied in knowledge, innovation or traditional practice (individual or collective) of actual value or associated with biochemical or genetic resources, whether or not they are protected by intellectual property rights or by *sui generis* registration systems. This law clearly states the need for informed consent on the part of the representatives of the locus where access is to take place and of all relevant authorities, as well as for guaranteed equitable sharing of benefits<sup>31</sup>.

29. Science, ‘Academy joins debate over DNA patents’, Volume 277, n° 5322, 4 July 1997, p. 41.

30. In: ‘Les savoirs traditionnels et la nécessité de leur assurer une protection appropriée en tant qu’objets de la propriété intellectuelle / Traditional knowledge and the need to ensure its appropriate protection under intellectual property systems’. Document drafted by the Group of Latin American and Caribbean Countries (GRULAC), WO/GA/26/9, WIPO General Assembly, 26th session, 25 September – 3 October 2000, Geneva.

31. Ibid.



## Peru

Draft protection regime for the collective knowledge of the indigenous peoples of Peru. This system would provide for the optional registration of the collective knowledge of indigenous peoples with respect to biological resources. Access to information listed on the register would be subject to authorizations granted by the indigenous peoples themselves, with the exception of information relative to the uses indigenous communities make of genetic resources and to the identity of the communities in question.

As regards the possible commercial use of such knowledge, the regime currently being contemplated would define as a prerequisite the signing of a licensing contract between the relevant indigenous communities and the persons interested in said use. Similarly, the draft protection regime provides a number of interesting definitions of collective knowledge, indigenous peoples, public domain, biological and other resources, with a view to specifying the various traits of the suggested regime<sup>32</sup>.

## Venezuela

The **Bolivarian Constitution of Venezuela** states, in Article 124:

Collective intellectual property rights over indigenous technical know-how and innovations are guaranteed and protected. All activities relating to genetic resources and the knowledge related thereto have as its aim the common good. The patenting of these resources and this traditional knowledge is banned.<sup>33</sup>

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32. Ibid.

33. Ibid.

## Conclusions

### 1) The most controversial aspects

- Requiring the **consent** of persons who allow research to be performed and provide to this end their own genetic material which will subsequently be patented. Furthermore, should persons giving their consent be aware, or be informed of the fact that their tissues are going to be used by a private corporate entity, and not by public research bodies?
- Asserting that persons providing their genetic material have rights to some form of **remuneration** (monetary, medical, etc.).
- **Stating the rights to health:**
  - of persons providing their genetic material, or more generally of populations used for research which then leads to the granting of patents;
  - of all citizens, as patents make access to care and to drugs more difficult or costly.
- Respecting the ethical principle according to which human bodies are **not property** and **can not be commercialized**, which derives from the principles of respect for human dignity, and of the human genome viewed as **heritage of humanity**.
- Granting to all scientists **access to research results**.
- **Sharing of benefits** arising from scientific progress: among scientists and between developed and developing countries.
- The emergence of **economic giants** and the development of **monopoly or dominant market positions**.
- Shifting of research from **public to private domain**: in whose interest is research performed?
- **Organizing research in other countries**, often developing countries, in order to obtain patents. Are patents acceptable when they are obtained under conditions of biomedical research contrary to universally accepted rules, or to the rules in force in the home country of the corporations seeking patents?
- Should patents on human genetic material be **product** patents or **process** patents?
- Desirability or legitimacy of patents on **expressed sequence tags**.
- Using genome-based knowledge for **non-peaceful uses** (to design weapons identifying targets with specific genetic profiles).

### 2) Suggested solutions

- **Informed consent** guarantees for persons providing their genetic material (Netherlands, Italy, Norway, Belgian CCB, Nuffield Council on Bioethics, EU Advisers Group, OAU)
- Improving **international legislation** in this field (Parliamentary Assembly of the Council of Europe)
- Developing a **code of conduct** for scientists which guarantees freedom of access to genetic resources and the sharing of benefits (Parliamentary Assembly of the Council of Europe)

- Adopting the **precautionary principle** as a common decision-making principle, once its content has been clearly defined (Parliamentary Assembly of the Council of Europe)
- Introduction of a **bioethical labeling** process for new technologies, bringing together a number of basic ethical principles, such as the non-commercialization of the human body (Parliamentary Assembly of the Council of Europe)
- Developing an **international convention on the use of living matter**, on a worldwide basis (Parliamentary Assembly of the Council of Europe)
- Adopting a supplementary **protocol** to the European Patent Convention which would specifically define the **criteria** to be used by national jurisdictions in the application of **exclusions on the grounds of morality** to the field of human and animal tissue use (some States party to the European Patent Convention, Nuffield Council on Bioethics).
- **Contractual arrangements** concerning **access** to genetic resources:
  - providing for **joint holding** of intellectual property rights (WIPO);
  - starting the **identity of the supplier** of said genetic resource and its derivatives, and annexing to access contracts provisions for the equitable sharing of benefits resulting from access to the above-mentioned components (Andean Pact, Peru).
- Developing **‘recommended contractual practices’, ‘guidelines’, and ‘model intellectual property provisions’** applicable to material transfer agreements and other contracts providing access to resources (WIPO).
- Identifying the **contributions most likely to give rise to rights on inventions** deriving from access to genetic resources (WIPO).
- **Joint research and development** seen as a **non-monetary** form of **benefit sharing** (WIPO).
- **Multilateral systems**: acquisition of intellectual property rights on genetic resources then placed within a multilateral system with access, in the framework of this multilateral system, to genetic resources protected by intellectual property rights (WIPO).
- **Non-granting or revocation** of patents obtained through **illegitimate access** to genetic resources (WIPO): definition of **principles for the international harmonization** of sanctions for illegitimate access.
- **Non-extensive protection** of intellectual property rights (Belgian CCB). Thus, process patents would be preferred to product patents.
- **Sui generis systems**: ‘relevant national authorities’ would only grant authorizations to exploit resources after having checked the consent of the populations concerned. **Fees** would be paid into a **fund** for the financing of projects defined with local communities in order to develop, preserve and sustainably use genetic resources (OAU).
- **Optional registration of information**: access to the information collected in a register would be subject to the authorization of the indigenous peoples’ concerned. Commercial use would only be allowed after the signing of a licensing contract between the indigenous peoples and the persons interested in the use of this information (Peru).
- **Exemptions for research**: protected ‘products’ (genetic resources) may be used free of charge and without constraints by scientists wishing to create new ‘varieties’ (OAU, Taiwan).