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

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Rapporteur: *Justice Michael Kirby*

Division of the Ethics of Science and Technology

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## 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 particular 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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Former Chairperson of the Inter-American Commission on Human Rights

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**KIRBY Justice (Mr) Michael** (Australia)

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Member of the Ethics Committee, Human Genome Organization (HUGO)  
Former President of the Courts of Appeal of New South Wales and Solomon Islands  
Former President of the International Commission of Jurists

## **Members of the IBC**

**BERLINGUER Prof. (Mr) Giovanni** (Italy)

Professor of Medicine  
Chairperson of the National Bioethics Committee  
Former Member of Parliament  
Former Director of the Department of Human and Animal Biology and of  
the post-graduate course in Bioethics, University of Rome

**GALJAARD Prof. (Mr) Hans** (The Netherlands)

Professor of Human Genetics  
Head of the Department of Clinical Genetics, University Hospital Rotterdam

**GUESSOUS-IDRISSI Dr (Mrs) Nouzha** (Morocco)

Professor and Head of Parasitology-Mycology Laboratory,  
Faculty of Medicine and Pharmacy of Casablanca  
Founding Member of the Moroccan Organization of Human Rights

**IDA Prof. (Mr) Ryuichi** (Japan)

Professor of International Law  
Rapporteur of the Committee of Regional Economic Development Law of  
the International Law Association

**JEAN (Mrs) Michèle** (Canada)

Adviser in programme development, Faculty of Higher Education, University of Montreal  
Former Special Adviser to the Minister of Foreign Affairs of Canada to the  
European Commission  
Former Vice-Minister of Health

**NOMBELA Prof. (Mr) D. César** (Spain)

Professor at the Faculty of Pharmacy, Universidad Complutense de Madrid  
Former President of the *Consejo Superior de Investigaciones Científicas*  
Former President of the Federation of European Microbiology Societies

**QUESTIAUX (Mrs) Nicole** (France)

Honorary Chairperson of Section of the State Council  
Vice-President of the National Consultative Ethics Committee for Health and Life Sciences  
Former Chairperson of the Permanent European Conference of National Ethics Committees  
Former Minister of Social Affairs

**ROUCOUNAS Prof. (Mr) Emmanuel** (Greece)  
 Professor of International Law  
 Chairman, National Commission of Patients' Rights  
 Member of the Academy of Athens  
 Member of the Institute of International Law, Geneva  
 Former member of the United Nations International Law Commission

**RUMBALL Prof. (Mrs) Sylvia** (New Zealand)  
 Professor of Chemistry  
 Assistant to the Vice-Chancellor (Equity and Ethics), Massey University  
 Former Dean, Faculty of Science, Massey University

## **Guests**

**Prof. (Mr) Samir K. BRAHMACHARI** (India)  
 Director of the Centre for Biochemical Technology, Delhi University Campus

## **Observers**

### **World Health Organization (WHO)**

**Dr Kathleen Strong**  
 Department of Management of Noncommunicable Diseases

## **UNESCO Secretariat**

Mr Georges B. KUTUKDJIAN  
 Director  
 Division of Human Sciences, Philosophy and the Ethics of Science and Technology

Mrs Marie-Christine BERCOT  
 Senior Programme Specialist  
 Division of Human Sciences, Philosophy and the Ethics of Science and Technology

Mrs Sabina COLOMBO  
 Assistant Programme Specialist  
 Division of Human Sciences, Philosophy and the Ethics of Science and Technology

Mrs Orio IKEBE  
 Associate Expert  
 Division of Human Sciences, Philosophy and the Ethics of Science and Technology

Mrs Valentina MILANO  
 Division of Human Sciences, Philosophy and the Ethics of Science and Technology

Mrs Léonie TREGUER  
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 Division of Human Sciences, Philosophy and the Ethics of Science and Technology

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**ANALYSIS OF INTERNATIONAL AND NATIONAL TEXTS**

Division of Human Sciences, Philosophy and  
the Ethics of Science and Technology