*Presidency of the Council of Ministers*


# DECLARATION ON THE POSSIBILITY OF PATENTING HUMAN EMBRYO CELLS

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1. The decision of the European Patent Office (EPO) to grant the University of Edinburgh, which collaborates with the US company Bio Transplant, patent number ER 695 351 covering the isolation and cultivation of stem cells from embryos and adult tissues and their genetic modification has again raised the ethical question of the production and utilization of embryos for experimental purposes, together with that of the patentability of human life for the purpose of commercial exploitation. It has given rise to extensive controversy and serious concern in the public opinion and institutions in Italy and Europe. The Italian National Bioethics Committee (in Italian CNB) has also on previous occasions expressed reservations concerning the patentability of living beings and on experiments performed on human embryos, as well as its disapproval of human cloning in particular (Rapporto sulla brevettabilità degli organismi vivent i of 19 November 1993,à e statuto dell'embrione umano of 22 June 1996, La clonazione of 17 October 1997).
The policy expressed in the above documents is consistent with the regulations adopted at the European and international level, to the drafting of which also the CNB made a contribution, namely:

1. Convention on Human Rights and Biomedicine of the Council of Europe (signed at Oviedo on 4 April 1997), art. 18 of which bans constituting human embryos for research purposes, and art. 21 prohibiting using the human body for profit;
2. Protocol on Human Cloning - also of the Council of Europe - (signed in Paris on 12 January 1998) banning the cloning of human beings;
3. Universal Declaration on the Human Genome and Human Rights (adopted by the UNESCO General Conference on 11 November 1997) which symbolically defines the human genome as the "common heritage of mankind", art. 11 of which states that "practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted".

2. The exceptional seriousness of the EPO decision nevertheless thus prompts the National Bioethics Committee, also in response to the request made by the Minister of Health, the Hon. Rosy Bindi, to "make a statement on the matter", in order to further clarify its position. Furthermore the rectification issued by the European Patent Office immediately after the event in order to specify that the scope of the patent does not include the human species nor therefore the cloning of human embryos, has no legal value insofar as it does not involve any amendment of the text which actually refers specifically, in paragraph 0011, to "all animal cells, especially of mammalian species, including human cells". The patent is thus legally effective in its present form, and in the practical consequences it entrains, even though the EPO's decision is liable to long and complicated appeal procedures.

This episode takes place in a context characterized by an alarming tendency to reduce the whole of biological life, including human life, to a mere object of patentable intellectual property and a marketable good, and by the risk of the gradual yielding of the political and juridical structures having the task of regulating the matter to the pressures exerted by the biotechnological industry.
In antithesis to this tendency it is necessary to emphasize the opposition of movements and environmental and humanitarian associations, of scientists, but above all, more simply, of civilized society, to the commercial exploitation of biological life and of the human body in particular. This recent led to the failure of the World Trade Organization summit meeting at Seattle and later, as the implementation of the guidelines set by the 1992 Rio de Janeiro Conference to the definition of a first International Protocol on Biosecurity adopted on 29 January last at Montreal.
The recent event could however induce in public opinion a widespread feeling of distrust in

the biomedical sciences, which could lead to undue obstacles to the freedom of science and in particular to research in the difficult fight against genetic disease and other pathologies affecting human beings.
For the very purpose of avoiding unjustified criticism of science it is necessary for its applications for industrial and commercial purposes to be evaluated as a function of the objectives pursued and the fundamental human values involved.

3. The CNB, on learning with satisfaction that the Italian government intends to appeal against the granting of the aforesaid patent, expresses the hope that the institutions and the political leaders will each play their specific role in guiding the applications of modern biotechnology. Furthermore, it reiterates its opposition to the patentability of the human being. In particular, as far as Italy is concerned, it recommends that:

1. The instrument for ratifying the Convention on Human Rights and Biomedicine, signed in April 1997 and which came into effect last December should be brought before parliament by the Italian government as soon as possible, together with the Integrative protocol on human cloning.
2. At the time of the transposition of the European Directive on Legal Protection of Biotechnological Inventions (Directive 98/44), the European text should be interpreted in such a way as to exclude all possible ambiguity regarding the illegality of patenting the human body in any of its parts and at any of its stages of development.

Lastly, it is necessary that, in addition to clear and accurate information concerning the biotechnological applications of science, and the definition of common regulations in the various European countries, that ways and means be found to ensure the transparency and public control over the modalities, subjects and purposes of the applications of biotechnological research whenever fundamental human and environmental values and interests are at stake. Furthermore, it is also urgent to identify strategies of collaboration among the private sector, the public institutions involved and the institutional bodies in order to orient the material utilization of the results of scientific research towards the promotion of significant and fairly shared human benefits.