Parliamentary Assembly
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COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Recommendation 1240 (1994)[1]

Protection and patentability of material of human origin

Parliamentary Assembly

1. The Assembly insists that human beings are subjects -not objects -of law, that the human body is inviolable and inalienable by virtue of its relationship to a person endowed with rights, and that limits must therefore be set to how it is used.

2. The draft bioethics convention of the Council of Europe (draft convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine) establishes the principle that the human body and its parts as such -that is, as they are found in the human body -shall not give rise to any financial gain.

3. The Assembly is aware of the rapid development of genetics and the striking range of its present and potential applications. Clearly, the immense resources invested in biotechnological research entail the protection of equipment, methods and products; such protection is the only way of safeguarding the development of research.

4. Patent law -more specifically, the provisions of the 1973 European Patent Convention -plays a role to this effect. Its purpose is to confer on the patent-holder not a right of ownership but an exploitation monopoly for a given period of time.

5. The debate today on protection of innovations involving living material focuses on this purpose and the legitimate character of patent law. This is because (in particular) of the granting of patents for transgenic production techniques based on animals, and also because of current controversies surrounding the possible acceptance or refusal of patents for DNA fragments, the industrial application and functions of which are not yet known.

6. The Assembly takes the view that fundamental debate on biotechnology must not be entirely confined to patent law.

7. The provisions of the European Patent Convention -signed prior to the birth of the first test-tube baby - were drafted, necessarily, without any deep reflection on prohibitions on and limitations to the commercialisation of the human body, its parts and products, or genetic mutation processes.

8. The provisions of this convention are today inadequate, notwithstanding certain restrictions which it provides for on grounds of public policy or morality which could lead to querying certain patent awards.

9. Moreover, the convention only addresses problems inherent in the relationship between human beings and biotechnology in terms of specific cases without theoretical perspective, and in an environment where patenting is the norm and commercial considerations are omnipresent; application of rules and their monitoring are the responsibility of civil servants and technicians.

10. A proposal for a directive of the European Union (legal protection of biotechnological inventions), though limited to the perspective of patents, has the merit of clearly specifying certain prohibitions in regard to the patentability of living material. However, the approach chosen is simplistic, as much because of the

1. Assembly debate on 14 April 1994 (15th Sitting) (see Doc. 7045, report of the Social, Health and Family Affairs Committee, Rapporteur: Mr Monfils; and Doc. 7068, opinion of the Committee on Science and Technology, Rapporteur: Mr Birraux). Text adopted by the Assembly on 14 April 1994 (15th Sitting).

European Union's substantive competence as because its action is geared to the harmonisation of the Single Market and development of Europe's competitiveness and trade. There remains, moreover, the possibility of commercialisation without patents of innovations involving living material, and the proposed directive does not provide for banning the commercialisation of non-patentable inventions.

11. In accordance with its previous Recommendations 1046 (1986), 1100 (1989) and 1160 (1991), the Assembly considers that ethical principles regarding living material should be a pre-requisite for providing scientists, in particular, with a legal framework to guide them in their work.

12. The task of deciding -in the light of social trends -on how to reconcile generally accepted moral standards, scientific research and commercial exploitation is fundamentally political; moreover, the appropriate principles are now set forth in the Council of Europe's draft bioethics convention.

13. In accordance with its Recommendations 1046 (1986), 1100 (1989) and 1160 (1991), the Assembly recommends that the Committee of Ministers:

13.1. adopt as soon as possible the text of the bioethics convention, refer it to the Parliamentary Assembly in good time for an opinion, and open it for signature without delay, thereby providing Europe with a reference to fundamental moral principles in the field of bioethics;

13.2. initiate the immediate preparation of a protocol to the draft convention, setting limits to the application of genetic manipulation to human beings, and transmit the text to the Parliamentary Assembly for an opinion;

13.3. assign the drafting of the protocol to its Steering Committee on Bioethics (CDBI), in which the Assembly should continue to be represented, with instructions to lay down a number of prohibitions, some of which may already be referred to in patent law, on inter alia:

a. processes for modifying the genetic identity of the human body for any non-therapeutic purpose contrary to human dignity;

b. techniques for cloning and producing chimeras; as well as on such manipulations as:

c. amalgamation of human gametes with those of a different species;transfer of human embryos to a different species, and vice versa;

d. production of an individualised, autonomous human being in the laboratory;

e. creation of children from persons of the same sex; and

f. sex selection for non-therapeutic purposes.

14. The Assembly also calls, in the interests of coherent development, for the European Patents Office to transmit to the Council of Europe an annual report for transmission to and debate by the Parliamentary Assembly on decisions on applications for patents relating to living material, and invites the Committee of Ministers to determine in consultation with the office the forms and procedures to be followed.