



PRESS RELEASE

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National Ethics Council issues Opinion on the patenting of biotechnological inventions

After several months of intensive debate the German National Ethics Council is today (Wednesday) issuing its Opinion *The Patenting of Biotechnological Inventions Involving the Use of Biological Material of Human Origin*.

The majority recommendation of the National Ethics Council is that the EU directive on the legal protection of biotechnological inventions should be transposed into national law as soon as possible. This recommendation is based on the view that the purpose of the draft law presented by the Federal Government is to limit the content that can be protected by a patent. The majority also recommends the adoption of measures – if necessary outside the field of patent law – to ensure that donors are given adequate information and that due evidence of their consent is furnished. There is no need for any further measures: the practical treatment of substance protection on the one hand and the limitation and concrete shaping of patent protection on the other can be left to patent practice. However, future trends and, in particular, the practice of the courts and patent offices should be closely monitored, especially with respect to the handling of substance protection and of the prohibition of granting on *ordre public* grounds, and as regards the facilitation of compulsory licensing provided for in the draft law. Any concerns arising should give rise to attempts to secure changes and clarifications at EU level.

In a more far-reaching position statement, eleven members of the Council recommend that Germany make full use of the existing arrangements allowing the adoption of individual national provisions, as in other EU Member States, and regret that considerations of time preclude a review of a number of fundamental elements of the directive. They therefore suggest that any necessary corrections be set out in the explanatory memorandum to the law and communicated to the European Commission as soon as possible. With regard to the legal instrument itself, they recommend that:

- the extent of protection afforded by a claim should be limited to the technical application of a function as specifically set forth in the description;

The German National Ethics Council

The German National Ethics Council's task is to provide a forum for interdisciplinary discourse between the natural sciences, medicine, theology and philosophy, and the social and legal sciences.

It expresses views on ethical issues relating to new developments in the field of the life sciences and on their consequences for the individual and society.

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- explicit provisions should be adopted stipulating that reproductive human substances, human organs, human embryonic stem cells and stem cell lines are not patentable;
- it should be obligatory to furnish evidence of the provenance of the biological substances of human and non-human origin used in each case;
- it should be compulsory to obtain free and informed donor consent; and
- the need for as restrictive as possible an interpretation of inventions should be emphasized.

The Opinion *The Patenting of Biotechnological Inventions Involving the Use of Biological Material of Human Origin* can be accessed online at:
<http://www.ethikrat.org/stellungnahmen/stellungnahmen.html>.