Europäische Akademie
zur Erforschung von Folgen
wissenschaftlich-technischer Entwicklungen
Bad Neuenahr-Ahrweiler GmbH

*Direktor:*
Professor Dr. Carl Friedrich Gethmann

**No. 21 (July 2000)**

# Newsletter

## *Akademie-Brief*

## Editorial

*The integration of European perspectives into its research is a goal that the Europäische Akademie is pursuing by several means. The Europäische Akademie attaches importance to the fact that "Europe" not only implies the countries of the European Union but moreover the countries of the European Council. To establish contacts in Central and Eastern European countries has therefore been a specially important task. In 1998 the Europäische Akademie initiated a study – conducted by Professor Dr. Gerhard Banse– on "Technology Assessment in "Central European and Eastern European Countries" (documented in: Graue Reihe No. 10) which laid a basis for further activities. A workshop in Prague (February 1999) "From an Information Society to a Knowledge Society" was organised in cooperation with the Academy of Sciences of the Czech Republic. The contacts established at these occasions led to a membership of Polish and Czech scientists in the project group "Electronic Signatures". In 1999 agreements on scientific cooperation were signed with the University Slaski in Katowice and with the Higher Schhol of Management in Tychy (Poland).*

*From 30 Aug. to 2 Sept. 2000 the Europäische Akademie is co-organiser of a german-russian Conference on Global Environmental Politics in Sankt Petersburg.*

*The Research Fellowship Programme offers scientists even from Central and Eastern European countries to take part in the research activities at the Europäische Akademie.*

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## Focus

### Moral Problems in the Patenting of Human Genes

*Felix Thiele*

The moral acceptability of patenting human genes is discussed on the basis of a terminological clarification; it is argued that human genes – but not mere gene-sequences – can be part of an invention and, therefore, may be patentable. Further, it is investigated whether patents on human genes a) amount to immoral 'patents on life', b) can be a massive hindrance to research, and c) lead to an unfair distribution of resources between industrialised and developing countries. It will be argued that a categorical ban on the patenting of human genes grom the moral point of view cannot be justified.

The issuing of a patent by the European Patent Office in Munich at the end of the year 1999 on a procedure for producing trans-genic animals from stem-cells triggered off a controversial public debate. The patent, which has since been amended, in its original wording would have afforded patent protection, among other things, to the production of trans-genic human beings from stem-cells. This, however, is not permissible according to the European Patent Convention. Thus the patent was changed solely because of a formal technicality. The on-going debate, however, does not confine itself to this incident but addresses in particular the topic of the moral acceptability of patenting human genes.

Patents are instruments of economic policy and are intended to serve the promotion of innovation. This includes the safeguarding of material investments and the protection of intellectual property ( e.g. inventions). In the latter case the inventor shall receive commensurate reward for his services in providing useful benefits to the community in general. The moral justification of patents is ultimately based upon the fact that by issuing patents it is possible to raise the general standard of prosperity. In this function patents have proven themselves over a considerable period of time. In individual cases, however, it may well be justified to raise moral objections against the issuing of a particular patent or against awarding patents in certain fields.

The patent law is subordinate to national and European legal provisions, which regulate research and the marketing of research results. Thus a patent does not authorise the owner of the patent to actually use the patented invention. Permission to use the invention is regulated by other valid regulations, e.g. a gene technology law or an animal protection law. This means, therefore, that a patent is merely an excluding right; i.e. the owner of the patent may exclude a third party from using the content of the patent and is entitled to issue licences (for which fees may be charged).

According to the European Patent Convention, patents cannot be awarded which violate public order or run contrary to generally accepted moral conventions. In this way it is ensured that in addition to explicit

bans on certain patents – e.g. the ban on the patenting of procedures for manipulating the human germ-line and the commercial use of human embryos – other, more far-reaching moral and legal considerations can also lead to the rejection of a particular patent application.

Procedures which lead to legally binding decisions should be as transparent as possible. Furthermore, the decisions themselves should be open to scrutiny. In the debate concerning the awarding of patents it has been repeatedly asserted that the European practice of awarding patents is not governed by and does not fulfil these well-proven principles of law. Though it must also be said that since various levels of appeal have been installed and patents can be contested through a number of appeal courts, it is difficult to comprehend the claim that the procedure for awarding patents is subject to a lack of control.

In order to avoid a confusion of terms one should differentiate between 'gene sequence' and 'gene'. The mere description of the base sequence in the DNA strand is understood as the knowledge of the 'gene sequence'; knowledge of a 'gene' demands not only the description of the sequence but also knowledge of the function of that sequence. Essential to the awarding of a patent is the presence of an invention. However, the mere description of a 'gene sequence' which is present in the human genome does not in itself constitute an invention but at best a discovery and thus, for the reasons given above, is not eligible for the awarding of a patent. However, if together with the description of the sequence of a gene the function of that gene is given, i.e. the 'gene' is described, then there is more to it than simply a discovery. The description of the function of a gene requires an intellectual achievement – e.g. the working out of a suitable experimental approach. Thus it would appear to be truly justified, in the case of a description of both the sequence *and* the function of a gene, to speak of protectable intellectual property. If the description of the sequence and function of a gene is also accompanied by a plan for its commercial application and utilisation, then in principle the prerequisites for awarding a patent are met.

If one assumes – as posited here – that genes may be patented in principle, it does not necessarily follow, however, that in a particular case, on examination of the patent application, the awarding of a patent may not be refused - e.g. on the grounds that the required degree of innovation is not met.

For the moral assessment of the patenting of human genes one should distinguish between those arguments which exclude the patenting of genes under any circumstances ( categorical bans) and those which only do this under certain circumstances (hypothetical bans).

a) The argument that 'patents on life' are immoral and that the patenting of plants and animals, but in particular of human genes, is morally unacceptable constitutes an attempt to establish a categorical ban. It is difficult to reconstruct a satisfactory definition of 'life'; but even according to the use of the word in everyday language a gene is not 'life' but only a component part of the same. Furthermore, a human being is not merely the sum of all his genes so that the patenting of all the genes of a human being would still not mean the patenting of life. Over and above this, the patent law does not provide the patent holder with the unrestricted right to make use of the patented living entity concerned. Thus, for example, if someone holds the patent for the production of trans-genic animals, this does not mean that he is also allowed to produce and use these trans-genic animals. The latter is only possible with permission which must be granted independent of the procedure for awarding the patent. Thus, in connection with the patenting of living entities, it is unfounded to speak of a new form of "slavery". Finally the patenting of a living entity or gene does not mean the patenting of a particular specimen of this living being but of the invention of a procedure connected with it. Therefore a particular human gene can be part of the patent-description. If, in addition to this, the gene concerned occurs in the human genome, no fees may be charged – contrary to occasional claims – because the gene concerned in the context of the individual genome does not constitute an invention on the part of the patent holder.

b) If no foundation can be established for a categorical ban on the patenting of human genes, it could nevertheless be possible that, in weighing the chances and risks involved in the patenting of genes, grave moral reservations may emerge which may make it seem morally advisable to put an end to this practice. The furtherance of bio-medical research is an accepted task, which is generally regarded as morally acceptable, perhaps even as morally advisable or necessary. If the patenting of human genes should lead to a massive hindrance to bio-medical research, which is widely asserted on the grounds that within a very short time the entire human genome will be patented and that the patents will be in the hands of a few life-science enterprises with overall control over the market, this would indeed speak against awarding patents on human genes.

In recent years high investments in bio-technology, to a large extent from private sources, have lead to a rapid increase in research activities in this field. Since these investments were made in anticipation of future profits, i.e. profits that do not yet exist, the investors are highly interested in safeguarding their investments. An instrument to this end is the application for a patent in order to safeguard the future utilisation of and benefits to be gained from research results. It is therefore to be assumed that a considerable proportion of bio-technological research today has only become possible at all because, among other things, the investments made could be safeguarded by patents. Whether a ban on the patenting of human genes would lead to a drop in investment in bio-technology remains for empirical examination.

The fear seems to be well-founded that the future development of bio-medical research could be impeded by the concentration of key patents (e.g. on a wide area of the human genome) in the hands of a small number of patent holders exclusively oriented towards commercial profit making. For the time being, however, the results of the human-genome-project only consist of mere sequences of the human genome and as such, for the reasons given above, should not be patented. In addition to this the European Patent Convention affords the possibility of counteracting this development by withdrawing existing patents and/or issuing compulsory licences *in the public interest.*

c) Finally, it is argued that the patenting of human genes and other genes would lead to an unfair distribution of resources between the rich, industrialised countries and the developing countries. In this connection the term "bio-colonialism" is used. It is correct

that awarding patents could lead to a morally unacceptable, unequal distribution of resources, which should be prevented or at least compensated for. It could happen, for example, that developing countries become dependent upon the use of patents in order to relieve widespread health problems, whereby the patent holders, and as such the beneficiaries from the licence fees, are located in the industrial countries. This, however, is already the case today. Many effective medicaments protected by patents are sold by the patent holders at a price which is acceptable in the industrialised countries but which is too expensive for the developing countries. This gives rise to the moral obligation to compensate for this unequal distribution and it seems indeed doubtful whether compensatory measures existing today, such as development aid, are sufficient. Nevertheless, few would demand a ban on the patenting of medicaments. For the sake of a consistent argumentation, however, the latter would have to be demanded by those who would prevent the patenting of genes on the grounds that this leads to an unfair distribution of resources.
In conclusion it may be stated that a categorical ban on the patenting of human genes from the moral point of view cannot be justified.

Dr. med. Felix Thiele M.Sc. is vice-director of the Europäische Akademie. His special field of research is Bio- and Medical Ethics.

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## Working groups

***Climate Prediction and Precautions***
The project group held two meetings on 12 May and 30 June 2000, which focused on methodological problems of evaluating climate change and on the discussion of principles and goals of climate politics.

Chair: Professor Dr. Meinhard Schröder (Universität Trier)

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***Electronic Signatures***
Between January and June 2000 the project group hold four meetings. In order to the fact that the project has a global European dimension, the last meeting took place in Prague. It was a platform to focus on specific problems in the Czech Republic while implementing standards and directives for electronic signatures. Invited guests were: Professor Dr. L. Tondl (Center for Science, Technology, Society Studies); Ing. Z. Bahenský (Association for Information Society) and Mag. A. Beneš (Mathematische-Physikalische Fakultät der Karlsuniversität)

Chair: Dr. Otto Ulrich (Bundesamt für Sicherheit in der Informationstechnik [BSI], Bonn)
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## News in Brief

***Lecture***
Professor Dr. Peter Zweifel (Zürich) was speaker at the sixth lecture that the Europäische Akademie organised in co-operation with the local savings-bank – the Kreissparkasse Ahrweiler. On 14 June 2000 Professor Zweifel introduced the audience at the Steigenberger Hotel in Bad Neuenahr into his subject: "Health costs and age structure. A new perspective". His challenging theses led to a lively discussion.

***Discussion circle " Medical Ethics"***
On 19 June 2000 Dr. Franz Knieps gave a lecture on "Rationing in Medicine? – Trends and Developments in Germany". Dr. Knieps is head of the department for politics at the public health insurance company AOK.

***Workshop***
"Embryo Experimentation in Europe" was the title of a workshop that the Europäische Akademie organised on 23 and 24 June 2000 in Bad Neuenahr-Ahrweiler. The participants discussed bio-medical, legal and philosophical aspects in a European perspective. Speakers were: Professor Dr. D. Beyleveld (University of Sheffield), Dr. Robin Lovell-Badge (Lab. Of Development Genetics NIMR London), Professor Dr. J. Holowka (Fundacja Zdrowie Warsaw), Professor Dr. G. Patzig (Universität Göttingen), Professor Dr. H. Lilie (Universität Halle), Professor Dr. D. Solter (Max-Planck-Institut für Immunbiologie Freiburg). The workshop will be documented in the *Graue Reihe*.

***Workshop "Open Source Software"***
The Europäische Akademie organised a workshop on "Open Source Software– A modell for a civil society?" in cooperation with the German UNESCO-Commission and the Institute "Technik-Theologie Naturwissenschaften". 60 participants met on 31 May and 1 June in the Evangelische Akademie Tutzing. Contributers were: V. Grassmuck (Humboldt-Universität Berlin), Professor Dr. A. Pfitzmann (TU Dresden), Professor Dr. L. Lessig (Harvard Law School), T. Jaeger/A. Metzger (Institut für Rechtsfragen der Open Source Software, München), Professor Dr. B. Lutterbeck (TU Berlin), Professor Dr. Jürgen Becker (GEMA, München), Professor Dr. T. Dreier (Universität Karlsruhe), J. Tauss MdB (Berlin), RA S. Ventroni (München), Professor H. F. Spinner (Universität Karlsruhe), C. Bieber (Universität Giessen), Dr. A. Dix (Landesbeauftragter f. d. Datenschutz Brandenburg), Professor Dr. R. Kuhlen (Universität Konstanz), Dr. M. Mayer MdB (München), Dr. R.-R. Wagner (Landesinstitut für Medienpädagogik Hannover).

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## Organs

***Partners Assembly***
The Partners Assembly (Gesellschafterversammlung) and the Managing Committee (Geschäftsführender Ausschuss) of the Europäische Akadmie GmbH held its 9th meeting on 3 July. The annual accounts were approved. In accordance with the statutes the chair changed to Professor Dr. W. Kröll (DLR).

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## Conferences

***International Conference: Global Environmental Politics***
*30 August - 2 September 2000, Sankt Petersburg (Russia), co-organised by the Europäische Akademie*
The German-Russian Conference aims at discussing the fields of sustainability, environmental ethics and environmental monitoring.
*Information:* Dr. Christian Langenbach
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christian.langenbach@dlr.de

**Implementation and Limits of Interdisciplinarity in European Technology Assessment**
*13-15 September 2000, Bad Neuenahr-Ahrweiler, organised by the Europäische Akademie*
The Europäische Akademie applied for financial support from the European Commission for this conference. In case of acceptance grants for young researchers (up to age 35) are available.

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or see our homepage:
www.europaeische-akademie-aw.de

***7th International FZK/TNO Conference on Contaminated Soil***
*18 to 22 September 2000, Leipzig*
The conference is organized by the Forschungszentrum Karlsruhe and the Netherlands Organisation for Applied Scientific Research in cooperation with the Umweltforschungszentrum Leipzig-Halle. The study group „Preventive Soil Protection" of the Europäische Akademie will present a lecture in the session „Strategic Considerations".

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## Lectures

Carl Friedrich Gethmann:

12.05.00 „Zur Amphibolie des Krankheitsbegriffs": Arbeitsgruppe „Gesundheitsstandards" der Berlin-Brandenburgischen Akademie der Wissenschaften, Berlin

24.05.00 „Proto-Ethik. Probleme der Ethik-Fundierung": Technische Universität Dresden, Institut für Philosophie

09.06.00 „Die TA-Strategie der Europäischen Akademie und das Modell der Arbeitsgruppen": Konferenz „Innovationen in der TA" im Bundesministerium für Bildung und Forschung, Bonn

11.07.00 „Die Einheit der praktischen Vernunft und die Vielheit der Kulturen": Bamberger Hegel Woche 2000, Universität Bamberg

Felix Thiele:

19.05.00 Die Patentierung menschlicher Gene – ein Diskussionsbeitrag. Session of the project group biotechnology, technology advisory board Rhineland-Palatinate, Marienthal

25.05.00 Ethische Probleme der grünen Gentechnik. Lecture and panel discussion at the "Gen-Welten" exhibtion, natural history museum Karlsruhe, Karlsruher Forum Ethik in Recht und Technik e.V.

07.06.00 Ethische Argumente gegen die Keimbahntherapie. History of science seminar, institute for history of medicine & Emil von Behring-library of history and ethics of medicine, Marburg

15.06.00 Genetische Diagnostik im Versicherungswesen. Ethische Aspekte. Forum Philosophicum, FernUni Hagen.

20.06.00 Stellungnahme zum „Diskussionsentwurf zu einer Richtlinie zur Präimplantationsdiagnostik" der Bundesärztekammer, Hearing at the ethics-commission of the medical association Bremen

27.06.00 Dürfen wir Menschen patentieren? Lecture organized in cooperation with the Kurverwaltung Bad Neuenahr

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## New Publications

Gerhard Banse: Die Genese des Projekts „TA Ost". In: Veda, Technika, Spolecnost – Theorie Vedy VIII(XXI)4, 1999, 95-112

Christian J. Langenbach: Virtuelle Bildung in der Informationsgesellschaft. In: Veda, Technika, Spolecnost – Theorie Vedy VIII(XXI)4, 1999, 61-75

## Personalities

Professor Dr. rer. pol. *Friedrich Breyer* studied Economics at the Freie Universität Berlin, in Heidelberg and at the London School of Economics. He graduated in 1974, finished his doctorate thesis in 1978 and his habilitation in 1983 at the University of Heidelberg. From 1986 to 1992 he was Associate Professor for Economics and Social Politics at the Open University of Hagen. Since 1992 he has been Full Professor of Public Economics at the University of Konstanz.
Professor Breyer is a member of several advisory boards such as the Scientific advisory board of the Federal Ministry for Economics and Technology. Since February 2000 he has held a research professorship at the German Institute for Economic Research (Deutsches Institut für Wirtschaftsforschung).
His special fields of research are economic theory of social policy, health economics and public choice.
Professor Breyer is a member of the project group "Human Genetics. Ethical questions and societal Consequences" of the Europäische Akademie.

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