

# **Patenting and ethical questions: What are the problems?**

*“Is there a Future for Patent Ethics Committees?”*

**Workshop**

**Hilton Hotel, Manchester Airport, 13<sup>th</sup> April, 2008**

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## **Norwegian committees dealing with science, medicine and technologies**

**- The Norwegian Biotechnology Advisory Board**

**- The National Committees for Research Ethics**

**- The National Committee for Medical Research Ethics (NEM)**

**# REKs**

**- The National Committee for Research Ethics in Science and Technology (NENT)**

**# The Norwegian Committee on Ethics of Patenting**

**- The National Committee for Research Ethics in the Social Sciences and the Humanities (NESH)**

**# The committee for human skeletons**

**- Committee for animal welfare**

## **Tasks for the National Committees for Research Ethics**

- \* to be a resource of competence in ethics in all fields of scientific research**
- \* to function as a watchtower and an adviser at the national level**
- \* to inform and advise scientific communities, governmental authorities and the general public**
- \* to coordinate relevant national activities and represent Norway in related international meetings and committees**
- \* to publish general ethical guidelines for researchers and research institutions**

### **The committees' work is aimed at:**

- \* researchers and research institutions**
- \* politicians and civil servants**
- \* relevant professions and organizations**
- \* the general public**

## **Norwegian laws dealing with ethical aspects in science, medicine and technologies**

- # **Biotechnology Act of 5 December 2003 No. 100 (Official translation)(Application of biotechnology in human medicine, etc.)**
- # **Gene Technology Act ((1993)(Official translation) (Relating to the production and use of genetically modified organism)**
  
- # **The Act relating to transplantation, hospital autopsies and the donation of bodies etc.**
- # **The Act concerning Termination of Pregnancy**
- # **The Act on personal health data filing systems and the processing of personal health data**
- # **The Act relating to the processing of personal data**
- # **The Patents Act**
- # **The Act concerning the welfare of animals.**
- # **The Biobank Act (2003-02-21-12)**
  
- # **The Ethics Research Act (2006-06-30-56)**

THE NATIONAL COMMITTEES FOR RESEARCH ETHICS was appointed by the Royal Ministry of Education, Research and Church Affairs on May 16, 1990. Its terms of reference include drawing up guidelines for research ethics in science and technology.

The National Committee for Research Ethics in the Sciences and Technology (NENT) is an independent body which, based on values shared by the general public, shall act as a national watch-post, inform and advise upon research ethics within the relevant fields of research.

**NENT** ▼  
*The National Committee for Research Ethics in Science and Technology*

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## **GUIDELINES FOR RESEARCH ETHICS IN SCIENCE AND TECHNOLOGY**



## **Practical aspects of research ethics**

- \* In planning projects and formulating applications for support**
- \* In accomplishing the project**
- \* In interactions with collaborators**
- \* In saving material and documentation**
- \* In publishing the results**
- \* In patenting**
- \* In relation to supervising**

## **The Norwegian Committee on Ethics of Patenting (NCEP)**

### **Appointed in 2004**

### **Mandate**

**The NCEP should support the The Norwegian Industrial Property Office (NIPO) in deciding if a patent application should be rejected based on a general ethical concern. NIPO should submit applications to NCEP for evaluation.**

### **Specific issues (exclusion criteria):**

- Cloning of humans**
- Changing genetic identity of human germ cells**
- Use of human embryos for industrial and commercial purposes**
- Genetic changes in animals which will cause suffering**

*NIPO has expressed that they are pleased with the activities of NCEP*

## Members and deputy members:

Dag E. Helland (leder)

*Professor, Institutt for molekylærbiologi, Universitetet i Bergen*

Cecilie M. Mejdell (nestleder)

*Forsker, Veterinærinstituttet, seksjon for husdyrhelse og velferd, Oslo*

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Vonne Lund

*Forsker ved veterinærinstituttet*

Ellen-Marie Forsberg (vara)

*Seniorforsker ved Arbeidsforskningsinstituttet, AFI, Oslo*

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*Professor i miljøkjemi, Universitet for miljø- og biovitenskap i Ås*

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## **Patentnemnd uten portefølje?**

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## **7.2 Expert group**

Roger Brownsword

*Professor of Law and Director of TELOS, King's College London  
Specialist adviser to the House of Lords Select Committee on Stems Cells and the House of Commons Science and Technology Committee; member of the Nuffield Council on Bioethics; member of the Law Panel for the National Research Assessment Exercise in 2008. Author of *Rights, Regulation and the Technological Revolution* (OUP, 2008)*

*Research interests: Contracts and the common law, legal theory, bioethics, and the regulation of technology*

David Townend

*Senior Lecturer, Sub-Dean (Postgraduate Studies) School of Law, University of Sheffield, Deputy Director of SIBLE (Sheffield Institute of Biotechnological Law and Ethics)*

*Research interests: Securitisation of Intellectual Property; Intellectual Property and Social Welfare – especially in relation to developing economies; Privacy and Data Protection – especially in relation to medical research, genetic information and biobanking; The Nature of Ownership – especially in relation to genetic information, grief and well-being*

Djims Milius

*MA, Ph.D.-student, assistant to David Townend, Sheffield Institute of Biotechnological Law and Ethics*

Tine Sommer

*PhD., Associate Professor, Department of Law, Aarhus School of Business, University of Aarhus. Member of the working group under the Danish Board of Technology behind *Recommendations for the patent system of the future* (2003–2005). Member of the steering group of the research project *“Comparative Genomics Focusing on Man and Pig”* (2002–2007). Report the Danish Council of*

*Ethics (2004) on Patent Law and the Human Genome*

*Research interests: EU-law and immaterial property law (especially biotechnology regulations)*

Graeme Laurie

*Professor, Director of the Arts and Humanities Research Council (AHRC), Research Centre for Studies in Intellectual Property and Technology Law, University of Edinburgh. Chair of the UK Biobank Ethics and Governance Council, and Chair of the Privacy Advisory Committee for Scotland. Co-author of *“Contemporary Intellectual Property: Law and Policy”*, Oxford University press, 2007 (with HL MacQueen and C Waelde)*

*Research interests: The role of law and ethics in responding to advances in medicine, science and technology*

## **7.3 Ekspertrapportene**

### **7.3.1 Ethics and Patenting: A Report for the Norwegian Advisory Board on Ethical Aspects of Patenting**

*Roger Brownsword*

#### *Introduction*

Characteristically, European patent regimes make express provision for exclusion against patentability on the ground that commercial exploitation of the invention would be contrary to ordre public or morality.<sup>1</sup> In line with this pattern, the relevant exclusion in Norwegian law provides that “patents are not to be given where their commercial exploitation would violate public order or morality”. However, where patent examiners claim to be primarily qualified to assess the “technical” features of an application, it is not clear that patent offices have the institutional competence to operate the moral exclusion. In response to this difficulty, Norway has taken the lead by establishing a specialist ethics advisory committee to assist the patent office in cases of moral difficulty.

Where such an ethics advisory committee (EAC) is established, the following three important questions arise:

<sup>1</sup> Director of TELOS and Professor of Law, King's College London; Honorary Professor in Law at the University of Sheffield.

<sup>2</sup> See Article 53(a) of the European Patent Convention and Article 6(1) of Directive 98/44/EC (on the legal protection of biotechnological inventions).

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**Robert Brownsword's three important questions:**

**1) In what circumstances should the Patent Office refer an application to the EAC**

**2) Where an application is referred to the EAC, by which ethical criteria should the EAC be guided in tendering an advice?**

**3) In what circumstance, and on what basis, should the Patent Office follow, or decline to follow, the advice of the EAC?**

### 7.3.4 *Report to the Norwegian Advisory Board on Ethical Aspects of Patenting: Ordre Public and Morality in a Patent Law Context*

*By Tine Sommer, The Aarhus School of Business, University of Aarhus, Denmark<sup>1</sup>*

#### I. Legal Statutes

##### *I. Overview*

The present study essentially focuses on the interpretation and scope of the ethical standard in patent law, which in its classic form reads: *Patents are not to be given where their commercial exploitation would be contrary to public order or morality.*<sup>2</sup> In particular, this study looks at the following issues:

- A. It appears that the Norwegian Patent Office (EPO) and the Ethical Committee have quite different interpretations of ethical relevance with regard to patents. What is a real ethical problem with regard to granting patents?
- B. How is violation of 'public order and morality' to be interpreted, and why should this only be taken to refer to detrimental environmental effects and serious disregard for animal welfare?
- C. What is the relevance of the precautionary principle, and uncertainty with regard to future consequences?
- D. The Ethical Committee also finds that there are grey areas between 'invention' and 'discovery' when granting patents on biological material, and that such grey areas may be ethically relevant.
- E. Furthermore, the committee has different interpretations as to what is satisfactory 'documentation' (e.g. of future, perhaps uncertain effects). While the committee adopts an interpretation that it perceives to be standard in scientific risk assessments, the Board apparently accepts as documentation a simple statement of the applicant that uncertain effects will not occur. While the Board argues that such statements make applicants legally accountable, the Ethical Committee argues that ethical assessments must be based on the best existing information and thus take account of scientific standards and findings.

**The Norwegian Committee on Ethics of Patenting is requesting the Parliament:**

**A. To clarify the mandate given the committee**

**B. To clarify interaction between NCEP and The Norwegian Industrial Property Office (NIPO)**

**C. To define procedures how advices from NCEP should be used by NIPO**