

# II BRISPE

Second Brazilian Meeting on Research Integrity,  
Science and Publication Ethics

IBqM/UFRJ & COOPE • FIOCRUZ • USP • PUCRS

Rio de Janeiro, São Paulo, Porto Alegre (May 28 - June 1, 2012)



# Intellectual property (IPR) and ethical issues in patenting in Biotechnology

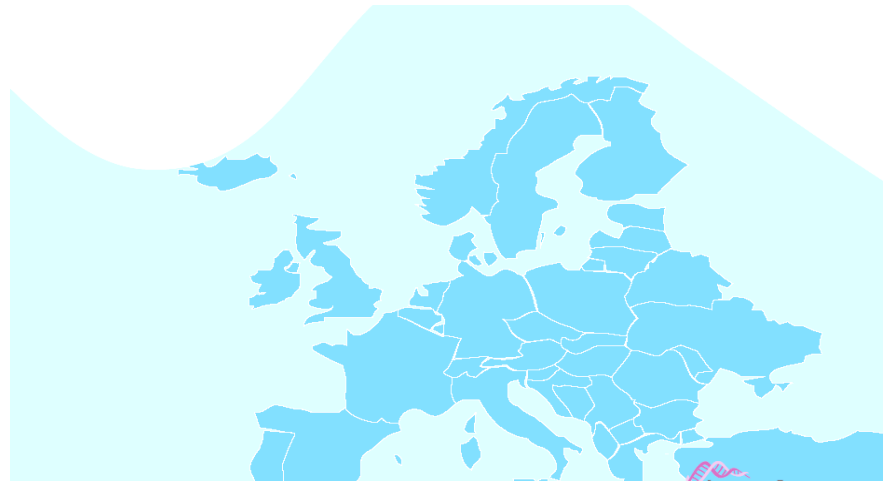
**Linda Nielsen, J.D.**

Professor, Dr. Juris of Global Law and Governance, University of Copenhagen, Faculty of Law

Vice President, European Group on Ethics in Science and New Technology (EGE)

Vice President, UNESCO's International Governmental Bioethics Committee (IGBC)

Former president of Copenhagen University







European Group on Ethics in  
Science and New Technologies  
(EGE)

EGE

The **EGE** is an **independent, pluralist and multidisciplinary** body which **advises** the European Commission on ethical aspects of science and new technologies in connection with the preparation and implementation of Community legislation or policies.

[http://europa.eu.int/comm/european\\_group\\_ethics/index\\_en.htm](http://europa.eu.int/comm/european_group_ethics/index_en.htm)

# European Charter of Fundamental Rights

## Dignity

- ❖ Respect for physical and mental integrity
- ❖ Free and informed consent
- ❖ Prohibition on making the human body a source of financial gain

## Freedoms

- ❖ Liberty, security and private life
- ❖ Protection of personal data

## Equality

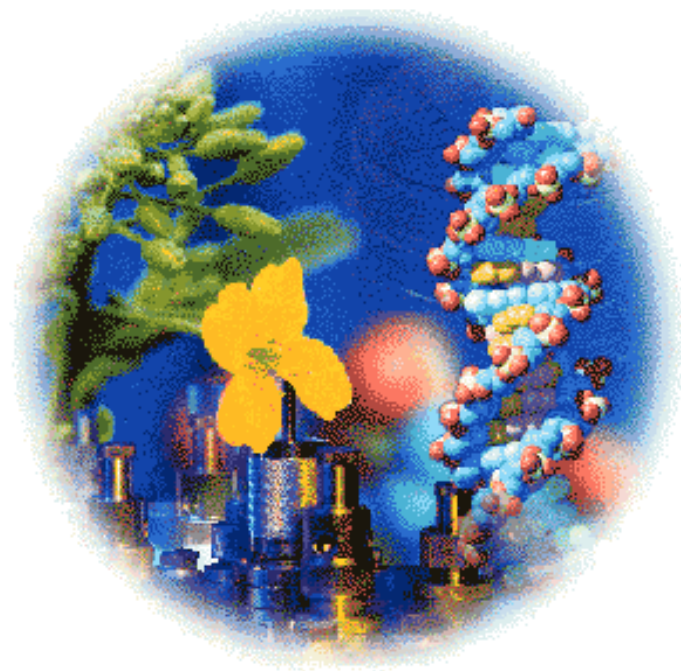
- ❖ Non-discrimination principle
- ❖ Respect for cultural and religious diversity
- ❖ The rights of vulnerable groups, i.e. children and the elderly

## Solidarity

- ❖ Access to preventive healthcare
- ❖ Right to benefit from medical treatment
- ❖ High level of human health protection

## Citizens' rights

## Justice



# Intellectual Property Rights

PATENTS  
EU

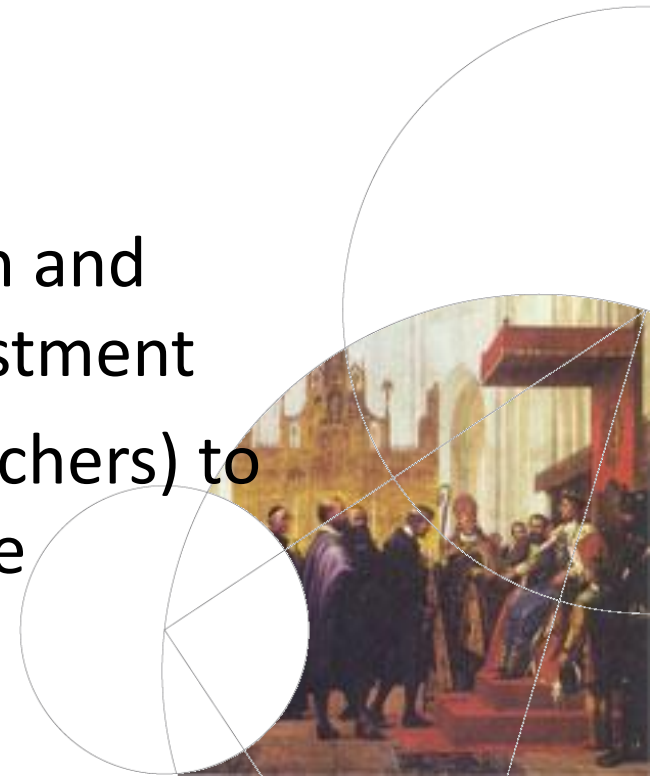




# EU Patent Directive

## Purpose

- Promote technological innovation and dissemination + attract investment
- Disclosure enables others (researchers) to build on achieved knowledge
- Legal certainty



# EU Patent Directive

## Method

- Exclusive right to commercial exploitation  
(not ownership or *right* to exploit)
- Description – product –process
- Criteria: Novelty, inventive step, industrial application (stricter than US)



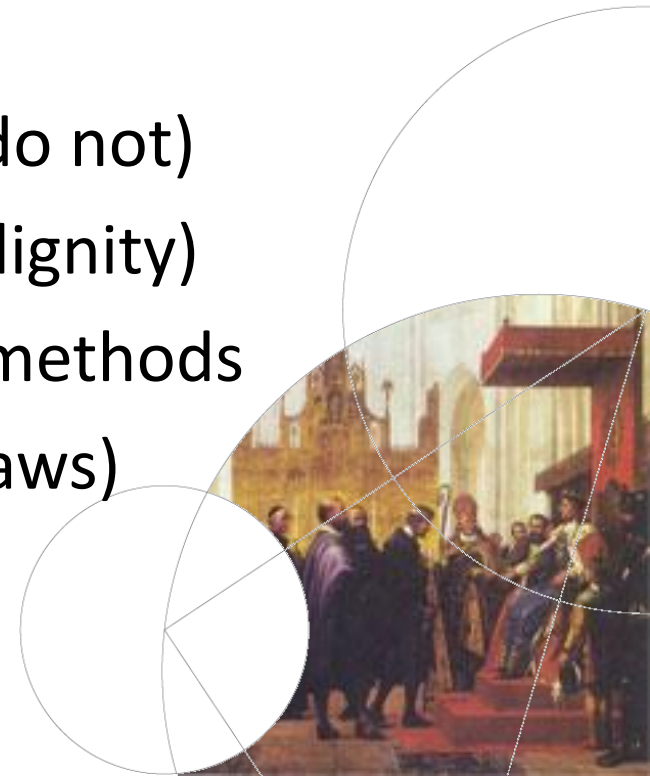


# EU Patent directive

**Ethics** - Included as concern (USA do not)

Exclusion: Ordre public – (human dignity)

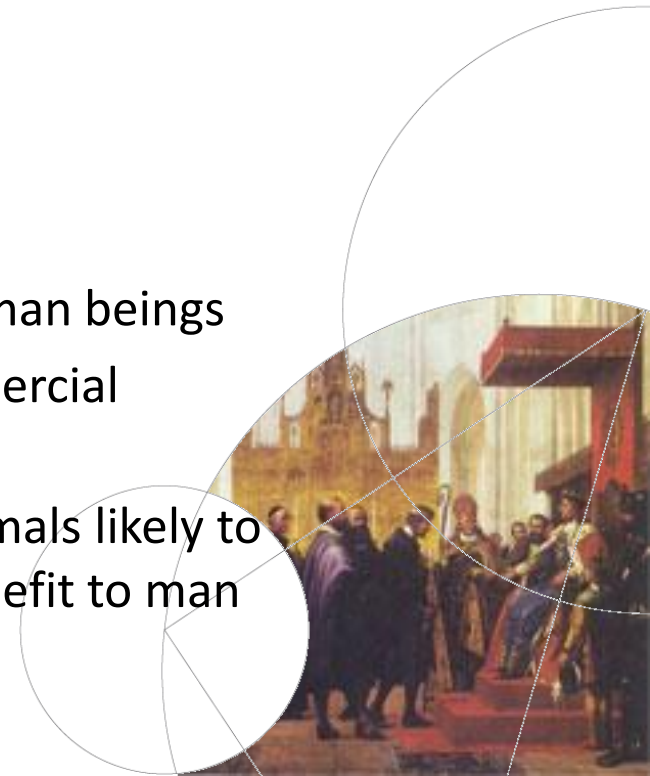
- Diagnostic, therapeutic, surgical methods
- Academic exemption (national laws)
- Specified exclusions



# EU Patent directive

## Specified exclusions – art 6

- Processes for cloning human beings
- Modifying the germ line genetic identity of human beings
- Uses of human embryos for industrial or commercial purposes
- Processes for modifying genetic identity of animals likely to cause them suffering without any substantial benefit to man or animal...



# EGE Opinion 16

EU Patent Directive art. 7:

EGE "evaluates all ethical aspects of biotechnology"

- Status of the embryo
- Avoid too broad patents
- European registry
- Ethical evaluation of patent applications



# IPR – Trends and challenges

- Open access controversial but gaining ground
  - EU, UNESCO
- Are patents "fit" for new inventions
  - Biotech, DNA, stem cells, IT etc??
- Patent system being questioned
  - Problem for openness between scientists?
  - Common heritage? Global aspects....

**DOCUMENTATION and INNOVATION needed**



# Research Integrity

## Regulatory options





# Regulatory options

- Laissez-faire
  - inefficient
- Leave to science
  - not universal
- Leave to universities
  - differences
  - sweep under the carpet?
- Central and independent body
  - avoid differences, build trust
  - costly (and slow?)



# Governance

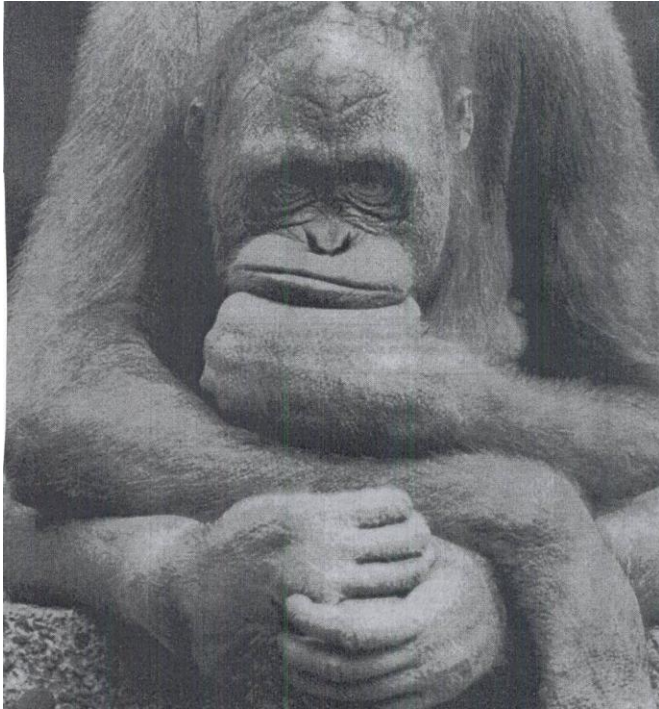
Reasons for governance

Methods of governance

Governance as a friend



# GOVERNANCE – WHY?



- PROTECT
  - persons
  - environment
  - values
- SECURE
  - ressources
  - research
  - technology
  - public trust
  - responsibility
  - clarity

# Governance – how?

- Laissez-faire
  - freedom
  - no protection
- Framework regulation
  - processes
  - flexibility
- Bans
  - protection
  - hard law
- Cautious regulatory
  - rather liberal
  - soft law

# **SOFT LAW**

## **EU CODE OF CONDUCT**

- **Responsible use of Nano**
- **Meaning**
- **Sustainability**
- **Precaution**
- **Inclusiveness**
- **Excellence**
- **Innovation**
- **Accountability**



# Processes

## Processes:

- ❖ Transparency
- ❖ Funding
- ❖ Information
- ❖ Dialogue



# GLOBAL GOVERNANCE

- EU expert group
- Report 2009
- *Global governance of science*
- Recommandations:
- Practises of ethical governance
- Critical reflections on means and ends on science
- Harmonize governance of science across national borders

# GLOBAL ETHICS

*needed!!!*

*Patents and research ethics crucial areas*

**GLOBAL GOVERNANCE??**



# Ethics and governance

## - what now?

- Engagement
  - – if you want to light a fire in others you must be burning!
- Be a giraf
  - – dangerous, no natural enemies and a big heart!!
- Ethics and values are essential
  - - for research and for researchers - and for governance

E-learning tool (open access)  
Bioethics and ethical decision-making (anti-corruption)  
[www.ethics-e-learning-com](http://www.ethics-e-learning-com)

***MAKE SUSTAINABLE PARTNERSHIPS***

*- Researchers, universities, countries*

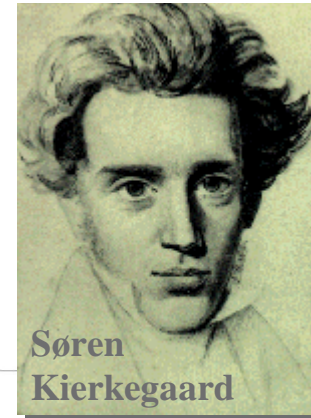




# En eventyrlig historie

- Denmark - Home of Fairytales...

BANG & OLUFSEN



Søren  
Kierkegaard

