



RemediE

Regenerative medicine in Europe: emerging needs and challenges in a global context

WP 6 – Hungary

EU and Global Bioethics: Intellectual property and cultural difference

Judit Sándor

Center for Ethics and Law in Biomedicine CELAB, Budapest

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Terminology

- Regenerative medicine is not (yet) used in legal classification of various biotechnological inventions
- However, the legal landscape and terms are subject to frequent changes eg. in the field of cloning, embryo research, “ therapeutic cloning” numerous terms underwent significant changes
- Recently within the Eu law the term “Advanced Therapy Medicinal Products” (ATMPs) regrouped new medicinal products based on genes (gene therapy), cells (cell therapy) and tissues (tissue engineering).

Methodology

- Ethical-legal comparison
- Mapping the differences on the legal landscape (between the EU, US & some selected Asian countries, China, India, South Korea)
- Analysis of landmark cases and policy papers
- Identification and analysis of the ethical issues involved
- Interviews
- Analysis of global issues

Case studies

European dimensions:

- EPO, ECJ, Selected pieces of national legislation

Comparative dimensions

- Cases selected from U.S. India, China, and South Korea (court cases, contested patents, ethics committees, policy documents)
- Focus: identification of cases where the moral dimensions of commercialization of various forms of regenerative medicine was the issue

Duality of legal norms

1. Human rights spirited norms

- Rules on human/ embryo research
- Dignity
- Non-commercialization

2. Multi-level legal norms on biotech innovations (patents)

- Commercial law
- IP law
- Property law
- Industrial use and profitability

Principle of non-commercialization

- Oviedo Convention (1997)

Article 21

- The human body and its parts shall not, as such, give rise to financial gain.

UNESCO 1997

- **Universal Declaration on Human**
- **Genome and Human Rights**

Article 4

- The human genome in its natural state shall not give rise to financial gains.

Principle of non-commercialization

“ As a matter of principle, human cells or tissues contained in advanced therapy medicinal products should be procured from voluntary and unpaid donation. Member States should be urged to take all necessary steps to encourage a strong public and non-profit sector involvement in the procurement of human cells or tissues,...”

Recital 15. of the Regulation on advanced therapy medicinal products

French National Ethics Committee

Avis No. 9 1987

- “Products of human origin are without price and therefore can neither be bought nor sold.
- Cells, which are a product of the human body, for that very reason **cannot be traded by the person who originated them**. However, that person may donate them, in the same way as blood is donated.”

French National Ethics Committee (2002)

- **Umbilical Cord Blood Banks for Autologous use or for Research**
- “... ethical difficulties arise because the concept of cord blood banks for exclusively autologous use carries with it a number of perils:
- The gravest danger is for society in so far as setting up such banks is likely to contradict the principle of solidarity, without which no society can survive.”

Heterogeneity of ethical concerns

Variations in the focus of prohibition:

- Research on embryos is forbidden
- Harvesting embryos and the creation of embryonic stem cell lines is forbidden
- Destruction is forbidden
- Only surplus embryos can be used for research (definition of surplus is not evident, however)
- Creation of embryos for research purposes is forbidden
- Source of funding is limited
- Separation of embryonic cells is restricted

Superficial agreement on prohibition – but the reasons are different

- Is it unethical because we instrumentalize the human body?
- Is it because we use *human embryos* or because we copy DNA or because the technique is not safe?
- Or is it unethical because it is experimental?
- Or because it is not useful?
- Is it unethical because we harvest many human eggs and make unnecessary suffering?
- Is it problematic only when it happens to human beings? Or the technique, as such, should be condemned?

South Korea

Bioethics and Safety Act (amended in 2009)

- Some of the key changes that are related to embryonic stem cell research include:
- SCNT will be allowed using human eggs that are left over after IVF
- The use of hES cells is now permitted (not derivation of them) for research purposes, but must be approved from IRB (previously, permission from the Ministry of Health and Welfare was required)
- Reproductive cloning and interspecies SCNT are banned.

Article 20.3 – Distribution of stem cell lines

- “(1) If a person who has established or imported the stem cell lines in accordance with article 20.2 plans to provide those lines, he/she shall undergo the Institutional Committee review as provided in the Ordinance of the Ministry for Health, Welfare and Family Affairs....
- (3) When a person supplies stem cell lines in accordance with paragraph (1) **it shall be supplied for free.** However, the provider may be reimbursed for the expenses for storage and distribution by the recipient.”

IP Law: Multi-level of regulation

- TRIPS (WTO)
- The European Patent Convention (EPC)
- London Agreement

It is an optional agreement aiming at reducing the costs relating to the translation of European patents.
- EC law (Directive 98/44/EC)
- Domestic patent law

Ethical components within IP Law

- Human dignity and integrity
- Patent law's own categories and ethics
- Invention/discovery
 - Industrial application
 - Industrial/commercial use
 - The rights of the patent holder

Implementing Regulations to the Convention on the Grant of European Patents

- Rule 29
- The human body and its elements
- (1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
- (2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

Ethical components within IP Law

- Human body
- The *ordre public/morality* clause
- The obligatory exclusions from patentability
- The inclusion of the EGE

Ethical components

- **General morality clause:**
- The performing of the invention must not be against *ordre public*/morality
- Directive 98/44/EC prohibits patentability of inventions whose industrial applications are contrary to "ordre public or morality" (Art.6 (1)).
- (This is not the case in US patent laws.)

Ethical components

- Paragraph 2 cites the examples where certain 'inventions' may be prohibited by this prohibition:
- “Processes for cloning human beings;
- processes for modifying the germ line genetic identity of human beings;
- uses of human embryos for industrial or commercial purposes;

Case: ZymoGenetics T 0898/05 (Haematopoietic cytokine receptor)

- “The concepts of "financial (commercial) gain" and of "profitable use" in relation to industrial applicability both tend to convey the same idea: patents being an incentive to innovation and economic success, the criterion of "industrial applicability" requires that a patent application describes its subject invention in sufficiently meaningful technical terms that it can be expected that the exclusive rights resulting from the grant of a patent will lead to some **financial or other commercial benefit**. (Case T 0898/05 of 7 July 2006, ex parte European Patent Office (EPO) Board of Appeal 3.3.08)

United Kingdom

- **Concept of the human body:**
- **Human totipotent cells**
- Human totipotent cells have the potential to develop into an entire human body. In view of this potential, such cells are not patentable because the human body at the various stages of its formation and development is excluded from patentability by Paragraph 3(a) of Schedule A2 to the Patents Act 1977. The Office will therefore not grant patents for human totipotent cells.

New Policy in the U.S.

- On March 9, 2009, President Barack Obama issued Executive Order (EO)13505 authorizing the Secretary of Health and Human Services, through the Director of NIH, to support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

NIH Draft Guidelines

March 2009

- Draft Guidelines would allow funding for research using only those human embryonic stem cells that were derived from embryos created by in vitro fertilization (IVF) for reproductive purposes and were no longer needed for that purpose.
- Although human embryonic stem cells are derived from embryos, such stem cells are not themselves human embryos.

Eligibility of Human Embryonic Stem Cells Derived from Human Embryos

- Human embryonic stem cells may be used in research using NIH funds, if the cells were derived from human embryos that were created for reproductive purposes, were no longer needed for this purpose, were donated for research purposes, and for which documentation for all of the following can be assured:
- All options pertaining to use of embryos no longer needed for reproductive purposes were explained to the potential donor(s).
- **No inducements were offered** for the donation.

Indian Council for Medical Research (2007)

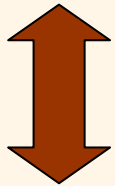
- “Research on stem cells/ lines and their applications may have considerable commercial value. Appropriate IPR protection may be considered on merits of each case. If the IPR is commercially exploited,
- a proportion of benefits shall be ploughed in to the community, which has directly or indirectly contributed to the IPR.
- Community includes all potential beneficiaries such as patient groups, research groups etc.”

New Landscape of Regulation

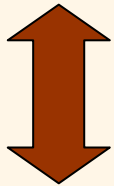
- Consumers participations is getting more and more important
- The relationship between licensing authorities,
- consumer-patient groups,
- researchers-care providers have changed significantly

Changing connections: Hierarchical model

- Regulation



- Licensing



- Researchers

- Researcher



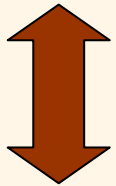
- Physicians



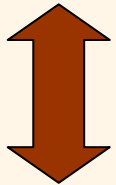
- Participants

Changing connections: Direct access

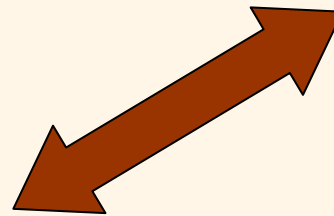
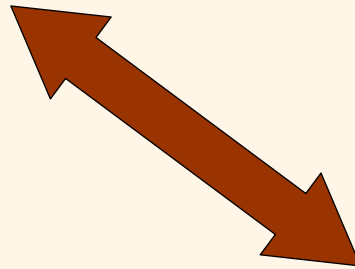
- Regulation



- Licensing



- Researchers



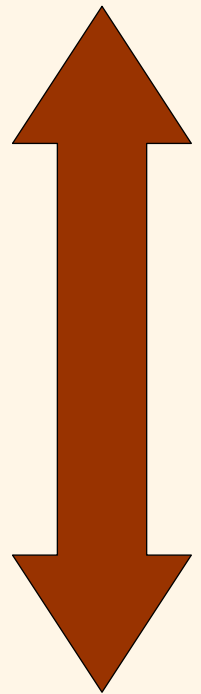
- Researcher



- Participants



- Physicians



Legal innovations

- Eugene Volokh Medical Self-Defense, Prohibited Experimental Therapies, and payment for Organs
- Even if this idea was challenged by many authors and its applicability in the field of stem cell therapies is limited the role of consumers and participants has changed in various biomedical fields in egg donation, in biobanks and in umbilical cord banks.

