nccr trade regulation
swiss national centre of competence in research

Future Challenges Regarding the International Regulation of IPRs and Biotechnology

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Human Genetic Resources

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WIPO – 25 November 2009

FNSNF Swiss National Science Foundation

The National Centres of Competence in Research (NCCR)
are a research instrument of
the Swiss National Science Foundation (SNSF)

Overview

1. Issues involved
2. Some corresponding facts
    1. HGR and trade
    2. HGR and the ethics debate
    3. HGR and the incoherence of the regulatory framework
    4. HGR and IPRs (Patents)
3. Conclusion

ISSUES INVOLVED

Environment of the Debate

1. Genetic engineering in HGR is of increasing (economic, commercial) importance.
2. There are intense ethical debates; but nevertheless genetic engineering in HGR appears more accepted by potential consumers than genetic engineering in Plant and Animal Genetic Resources.
3. Coherence amongst (domestic and international) regulations is needed
4. International patent law does not intervene in the debate

Questions

- How does (international) regulation deal (or not) with the increasing importance and trade relevance of HGR products?
- In ethical questions, is there a consensus on core issues that could form the basis for further harmonisation?
- How are trade and innovation needs, ethical sensitivities, and developmental concerns being dealt with in this field? Are regulations interfaced and adequate?
- What is the appropriate level of regulation?

INNOVATION IN HUMAN GENETIC RESOURCES AND TRADE

Some Examples of Traded Products

Damaris Jankowski

- Diagnostics
  - Molecular diagnostic tests
  - Personalized treatments
- Gene-therapy
  - Methods to deliver information into target cell
  - Anti-cancer therapy
- Xeno-transplantation
  - Organs from Humanized animals (pigs)

- Xeno-Products
  - Chimeric anti-bodies
  - Humanized antibodies (Xeno-mouse technology)
- Biologics
  - Pharming: transgenic animals and plants (incl. Human-animal and human plant chimeras) producing useful antibodies
- Stem-cell lines
  - Differentiated cell-lines for various diseases from embrionic stem-cells
  - Method for direct targeting of stem cells into organ

There is intense research into human genetic resources.
International trade in products based on human genetic resources is increasing.

Is there trade distortion by disharmonised patent regulation, and therefore a need to harmonise the patent regimes?

RESEARCH INTO HUMAN GENETIC RESOURCES AND THE ETHICAL DEBATE

Debates in a Nutshell

Historical

Since the emergence of systematic scientific research, research on the human body is subjected to specific rules (Human dignity, PIC discussion; HR in general).

Regarding the technology as such

Research and application that invade human germ-cells; i.e. production of embryonic stem-cells; cloning

Regarding IP – Patenting

Consent to patenting of inventions based upon an individual's or a small group's genetic information.

Need for specific exclusions?

Research into HGR is ethically sensitive.

Research invading human germ cells (“the core of life”) is the most ethically debated (slippery slope argument).

The Approach to Ethical Questions in International Public Law on Human Genetics Research

Cintia Busse

Global Fora and Instruments

- Professional/scientific associations (e.g. World Medical Association):
  - Guidelines and Codes on best practices in biomedical research (e.g. Helsinki Declaration 1965, last revised in 2008
- UNESCO:
  - Universal Declaration on the Human Genome and Human Rights (1997)
  - International Declaration on Human Genetic Data (2003)
  - Universal Declaration on Bioethics and Human Rights (2005)
- UN General Assembly:
  - Declaration on Human Cloning (2005)

Regional Fora and Instruments

- Council of Europe
  - European Convention on Human Rights and Biomedicine (Oviedo Convention)
    - Protocol on Human Cloning (2001)
    - Protocol on Transplantation of Organs and Tissues of Human Origin (2002)
    - Protocol on Biomedical Research (2005)

- European Union
  - European Charter of Fundamental Rights (Nice, 7 December 2000)
    - Art. 3: Right to the integrity of the person

Consensus on Core Issues ?

- Right to prior and informed consent
- Right to privacy and confidentiality
- Right to information and to be protected from disclosure of information
- Prohibition of discrimination based on genetic traits
- Right to reparation for harm caused by biotechnology

- Prohibition of human reproductive cloning
  - But absolute lack of agreement on therapeutic cloning.
- Prohibition of non-therapeutic eugenic practices
  - And therapeutic eugenic practices?
- Prohibition of using the human body, or any part of it, for economic profit
  - Controversial if the human body part, or a *specific* human body part, is basis for or integrated in an invention.

If the international ethical debate is taken as an indicator for the possible harmonization of the international framework regarding research into HGRs and the patenting of respective inventions, the conclusion is that there is disagreement, in particular regarding therapeutic cloning and/or the use of embryonic stem-cells.

INCOHERENCE OF THE REGULATORY FRAMEWORK

Incoherence Regulatory Framework

- Research allowance, patenting and commercialisation (safety) regulations often differ within one country
- **Either** patents loose their (direct) function of being market based tools (when inventions are patented while they cannot be commercialised) and get too strong public attention (being the first to 'deal' with it); **or**, if they are stricter than the rest of the regulatory framework, they are so without reason

ISSUES OF PATENTING HUMAN GENETICS

HGR, IPRs & HR: PIC

- Prior Informed Consent to donation, to research, to patenting, to commericialisation
- PIC to patenting: Human dignity and privacy rights have elements calling in favor; yet the overall balance of human rights does not appear to call for a PIC requirement

HGR, Patents & TRIPS: Trade distortion v. ethical objections

- Increasing trade + rather large public acceptance of medicinal products
- TRIPS' silence leads to different national approaches
- With increasing trade, this will logically lead to increasing trade distortion
- Yet can TRIPS find a consensus?
- Exclusion of the human 'organism'?

HGR & International Patent Law: TRIPS and its Silence

- **What** does it mean 'TRIPS is silent'?
  - Human genetic inventions fall within Article 27 § 1? Or:
  - If animals and plants may be excluded, then 'human' as well?
- **Can** TRIPS stay out of the debate, being silent?
  - Legal insecurity? Trade distortion?
  - Exclusion of the human body – interfacing with UNESCO and HR?
- **Should** TRIPS stay silent?
  - Ethically too divergent views?
  - Not trade relevant yet anyway?
  - Impossible to interface with other areas of regulation because these are fragmented and no international agreement exists (cf. cloning)

CONCLUSIONS

Conclusion(s)

- Trade distorting effects of disharmonised patent regulations are bound to increase future
- Ethical objections vary. Nevertheless acceptance of products appears large.
- Harmonisation appears recommendable; yet countries may not be ready/willing
- Patent laws should not be stricter or wider than regulations on research and commercialisation
- TRIPS as today creates legal uncertainty and should reflect internationally accepted, core ethical agreements.