Seminar on Current Challenges in Intellectual Property Rights and Biotechnology

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Intellectual Property and Bioethics

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World Intellectual Property Organization

Overview

- Bioethics and IP
- Core principles
- Four main sets of issues

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Biotechnology

>> Aims to serve basic human needs such as human health, food and a safe environment

>> Touches on fundamental values, such as human dignity and the genetic integrity of humanity

>> Raises concerns e.g. over equitable access to the fruits of new technologies, the consent of those involved in research

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Bioethics

- Applied ethics: application of theoretical ethical tools and ethical norms to address moral choices
- Ethical implications of biological research and the biological and medical applications of research
- Issues: e.g. consent of the donor of human genetic material, access to health care and distribution of health resources, equitable access to the outcomes of biological research, the dignity of the human being, beginning-of-life and end-of-life issues, animal protection, environmental ethics

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Intellectual property protection

- Legal rights resulting from intellectual activity in the industrial, scientific, literary and artistic field
- Patents, plant breeders rights or plant variety systems, copyright, trademarks, law of confidentiality and the protection of undisclosed information, protection of test data, unfair competition
- In international treaties, bioethical questions are barely dealt with, concepts of “invention”, “morality” and “ordre public” left for national authorities to define

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Core principles

- Transparency
- Consent
- Equitable sharing of benefits
- Pluralism

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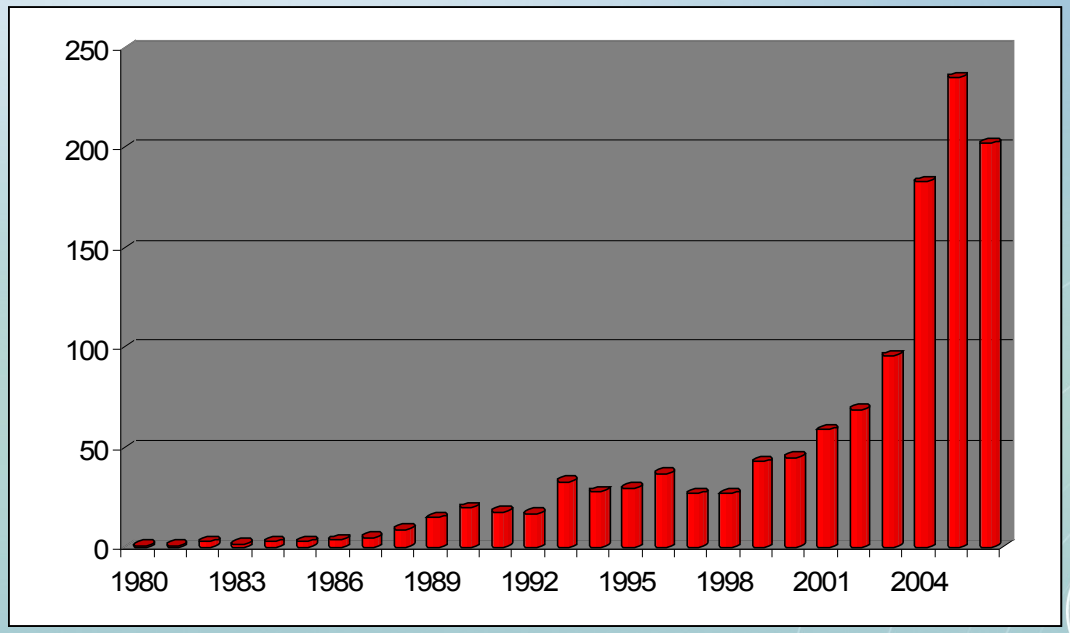
Core principle: Transparency

International patent applications on human, animal or plant cell lines by year of publication (Source: Patentscope)



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Transparency

Basis for ethical scrutiny of relevant technologies

Patent information systems used to monitor:

- Trends and background in key technology
- State of the art in key technology
- Research and patenting activities of firms/institutions/individuals

Need for improved use/access of patent information, and value-added information products to guide policymaking

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Core principle: Consent

- Moore case: Hairy cell leukemia
- Universal Declaration on Bioethics and Human Rights: "Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned"
- CBD: condition of access to genetic material of plant, animal or microbial origin

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Core principle: Equitable sharing of benefits

- Universal Declaration on Bioethics and Human Rights: “equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries”
- CBD
- FAO International Treaty on Plant Genetic Resources for Food and Agriculture

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Core principle: pluralism, conciliating different value systems

- A community's sense of morality and the values of that community may guide ethical judgments
- Technology considered immoral in one country may be considered morally acceptable in another
- IP systems leave interpretation and application of exceptions in patent law for technology that is contrary to morality to national law

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Key aspects of IP and bioethics

- Ethical aspects of a technology as such
- Ethical aspects of national authorities granting exclusive IP rights over a technology
- Ethical aspects of seeking exclusive IP rights
- Ethical aspects of how an IP right holder should exercise exclusive rights over a patent

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Ethical aspects of the technology as such

Should research be permitted? ↔ Should the results of research be patented?

Examples: Stem cell research, genetic use restriction technologies

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Ethical aspects of granting exclusive IP rights over a technology

- Patentability questions
- Exceptions
  - On the basis of morality or ordre public
  - Methods of medical treatment
  - (Higher) life forms

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Ethical aspects of seeking exclusive IP rights over a technology

- Actions of individual actors: a firm, a research institution, a university
- Whether or not to pursue a patent for a particular invention
  - E.g.: should a publicly funded agency patent its research results on a new vaccine production technique?
  - If traditional knowledge was legally obtained and led to an invention: can the actions of a patent applicant in obtaining and using that knowledge be considered unethical?

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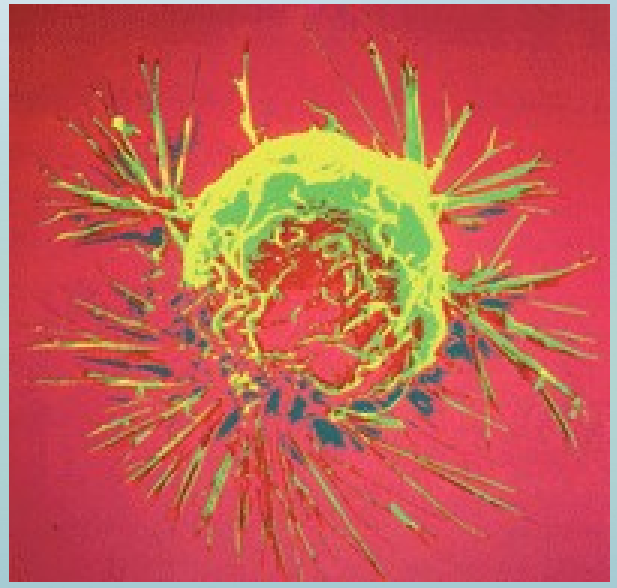
Ethical aspects of exercising exclusive rights over a technology



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Conclusions

- Choices by the State or by government authorities versus behavior of individuals, firms, institutions
- Distinguish ethical and legal aspects, interaction between both

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