

## Ownership and distribution

Ethical issues in patenting

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## Ethics in science

- Ethics in “Science” and “Nature”



## “Ethics” in Science and Nature

Most frequently discussed subjects 2000-2010:

- Patents
- Stem cells
- Scientific integrity (new NIH guidelines 2005)
- Research ethics (biobanks, human subjects)
- Synthetic biology (more recently)

## Scientists influence policy...

### When Patents Threaten Science

Lori Andrews,<sup>1\*</sup> Jordan Paradise,<sup>2</sup> Timothy Holbrook,<sup>1</sup> Danielle Bochner<sup>1</sup>

#### Conclusion

[ ] “Scientists can be influential by helping policy-makers understand that open access to basic laws of nature, products of nature, and mathematical formulae is necessary for scientists to explore and innovate.”

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## Patents, ownership, distribution

Money, money, money

We have more than one moral principle  
 Reasonable people can disagree on their priority  
 Legitimate interests, just distribution

PLURALISM  
 DIVERSITY

## Content

- Introduction to ethical reasoning
- Ethical issues in patenting

## Content

### Introduction to ethical reasoning

- Reasoning for and against actions: why and how?
- The role of scientists concerning ethical questions: (only) name facts or participate in ethical discussion?
- Interdisciplinary ethics

### Introduction to ethical reasoning

- Norms, morality: intuitions, family values, traditions
- Ethics: science of the justification how to act
- Ethics is particularly important in a pluralistic society, which is composed of different political, religious, philosophical etc. «communities», that hold distinct ideas about values and priorities.
- Different values, who decides?
  - The right of the strongest (make war, economic pressure, psychological pressure )
  - Negotiate, convince each other based on ethical arguments/reasoning, procedural ethics (voting processes, democracy etc.)

## Ethical arguments

- Different ways to justify actions
  - Deontological: "do right", religious ethics, ethics codex of professional groups, Kant's categorical imperative, 10 commandments ("thou shalt not kill" etc.), «golden rule»,
  - Based on consequences (consequentialist): "do good", don't harm. Problems:
    - Who defines what is benefit and harm?
    - Who is considered: Benefit and harm for whom (the own country, humans, animals, nature )?
    - Utilitarianism: should one give priority to the greatest good for the greatest number of people and sacrifice for that a few people who might die or be seriously harmed?



## Interdisciplinary bioethics: why and how?

### Interdisciplinary bioethics: why?

- Some reasons in favor of interdisciplinary bioethics:
- Good ethics needs good facts
  - Ethics can boost science
  - Views from several disciplines help to find globally acceptable solutions

## Interdisciplinary bioethics: how?

Some examples for interdisciplinary bioethics:

- A first step model
- More advanced models
  - *ELSI research*

## Interdisciplinary ethics: a limited model

- In this model, the scientist has a central, yet very limited role: **that of a "problem-maker"**. Biologists are basically seen as creating ethical quandaries for others to solve.
- This is reflected in the style of "polite" interdisciplinarity of some bioethical meetings.
- The scientist on duty is kindly requested to explain the subject-matter of, say, gene technology or synthetic biology or whatever is the topic of the day. Then, there is a change of scene: philosophers and theologians explain to the rest of us what one must think in moral terms about these new developments.

Adapted from Alex Mauron, Geneva

## Interdisciplinary ethics: a limited model

### The "problem-maker" model (continued)

- If a scientist intervenes not simply to make a factual point but to offer an ethical argument, one sometimes senses a slight irritation, as if the scientist was reaching beyond his expertise towards ethical questions that aren't his business.
- There is an assumption that scientists are there to provide the bare facts and that it is then for ethicists and moralists to conduct the moral analysis and come up with the normative answers.

Adapted from Alex Mauron, Geneva

## Interdisciplinary bioethics: how?

"Truly" interdisciplinary bioethics:

- More advanced models, for example *ELSI research*

## Bioethics – different approaches

Two important distinctions:

- Ethics in moral communities
  - Religious communities, human rights activists, personal ethics
- Ethics in a pluralistic society
  - Binding international law (ratified conventions) and soft law (recommendations of the UN, Council of Europe), national laws are changing and influenced by societal norms and constant dialogue about them

## Bioethics – different approaches

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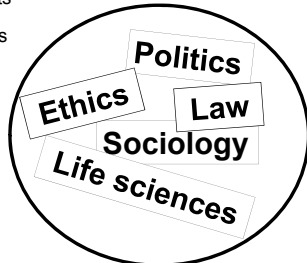
**We are all concerned**

We need to find ethical solutions that are acceptable in a global context!

## Bioethics – different approaches

Norms in a pluralistic society, different layers

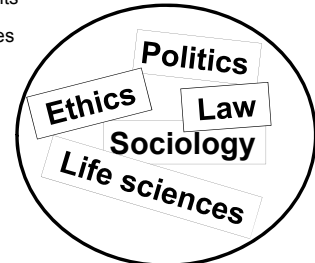
- Ethical arguments
- Ethical guidelines
- Laws



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## Bioethics – different approaches

Ethics and policy:

- **Reactions to sociocultural transformations and the advancement of science**
  - *Different stakeholders feel their interests threatened*
    - Public, patient interest groups etc.: Fear about danger of biotechnology, abuse of genetic testing; fear about exploitation
    - The industry and researchers: fear that research and advances in biotechnology might be hampered
  - *The law has different roles*
    - Prevention (e.g. of human rights abuses)
    - Harmonization of practice (important to advance research)
    - Creation of trust concerning new technologies (increase of acceptance for and participation in research of the population)

## The role of (biotechnology, health) law

### Law versus ethics

- Legal regulation and jurisprudence (court decisions) take time and are often "late": they come only after the events.
- Regulation starts with ethical discussion and the question: "do we really need a law?"
- Laws might be too rigid to deal with social realities (discussion about euthanasia laws)

## Content

- Introduction to ethical reasoning
- Ethical issues in patenting
  - Ownership rights
  - Distribution

- Ownership:
  - Why ?
  - What ?
- Distribution:
  - Knowledge
  - Goods
  - Incentives

Property is “a bundle of rights”  
(Honoré 1961)

- Use of biological samples
- Anonymisation of samples
- Transfer of samples
- Commercialisation (patents, benefit sharing)
- Destruction of samples
- etc.

What provides:

- ownership rights?
- the right to use something?
- the right to receive something?

Purchase?  
Labor?  
Utility?  
Need?  
Skill?  
Discovery?  
Invention?

Utility (in economics)

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Utility: how much satisfaction is experienced by someone because of a certain good (chocolate, medication ).

Economists define utility based on how much people are willing to pay for different goods.

« Everything has either a *price* or a *dignity*.

Whatever has a price can be replaced by something else as its equivalent; on the other hand, whatever is above all price, and therefore admits of no equivalent, has a dignity. But that which constitutes the condition under which alone something can be an end in itself does not have mere relative worth, i.e., price, but an intrinsic worth, i.e., a dignity”

Immanuel Kant, Groundworks of the metaphysics of morals

A patent does not confer ownership, but the (exclusive) right to prevent others from exploiting <insert something here>

What does this change?

- “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.” (Directive 98-44-EC Art 5.1)
- “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.”(Directive 98-44-EC Art 5.2)

## Directive 98-44-EC Art. 6

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
  - (a) processes for cloning human beings;
  - (b) processes for modifying the germ line genetic identity of human beings;
  - (c) uses of human embryos for industrial or commercial purposes;
  - (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

## Conclusion 1

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- We own things because we *deserve* to own them
  - But we diverge in part on what makes it so
  - This raises issues of utility and fairness
- We own things *which are such that they can be owned*
  - But we diverge in part on what makes it so
  - This raises issues of respect for persons (and living things?) and of utility

## Distributing ideas

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- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>• Science is a collaborative enterprise, and thrives on the free exchange of ideas</li> </ul> | <ul style="list-style-type: none"> <li>• Patenting may discourage disclosure</li> </ul>          |
| ?  |  |
| <ul style="list-style-type: none"> <li>• Science should be / needs to be curiosity-driven</li> </ul>                                 | <ul style="list-style-type: none"> <li>• Patenting leads to incentive-driven research</li> </ul> |

## Willingness to help

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- Most people would be more likely to help a car accident victim (s.o. close) than people in need far away ("please donate ")

## Problems with patent system

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- Exclusion of poor people
- Neglect of diseases concentrated in low-income countries
- Bias towards maintenance drugs
  - Existing patent systems make symptom-relieving drugs most profitable and thereby biases research and development against curative medicines and especially vaccines
- Wastefulness
  - Innovators presently have to cover the cost to file and litigate patents in many countries—globally, people bear huge losses from foregone sales above marginal cost and below present monopoly price

Banerjee A., Hollis A., Pogge T.: The Health Impact Fund: incentives for improving access to medicines. Lancet 2010

## Problems with patent system

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- Counterfeiting
- Drug resistance from diluted version of counterfeit
- Excessive marketing
  - extensive efforts to improve sales by influencing prescription patterns of physicians, irrespective of therapeutic improvement.
- The last mile problem
  - Pharmaceutical companies have poor incentives to promote the optimum use of their medicine and to ensure that their drugs reach those (and only those) who need them

Banerjee A., Hollis A., Pogge T.: The Health Impact Fund: incentives for improving access to medicines. Lancet 2010

## Distributing goods

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<p><b>Patenting</b></p> <ul style="list-style-type: none"> <li>• Rewards discovery</li> <li>• Monopoly pricing</li> <li>• Pay-per-use</li> <li>• User payment</li> </ul>	<p><b>Health impact fund</b></p> <ul style="list-style-type: none"> <li>• Rewards discovery <i>and distribution</i></li> <li>• Cost of production</li> <li>• Pay-per-utility</li> <li>• Third party payer</li> </ul>
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Both reward innovation  
Both look to consequences  
Both can achieve fairness for innovators  
The question here is *what works* ?  
And *what can acheive fairness to users* ?

## Patenting of medication

Do good

Do right

<p>+Patenting is necessary in order to create an incentive for investing research and development that will lead to various benefits; without the incentive provided by patenting that investment will not be made.</p> <p>- Patenting will have destructive economic effects on social structures (e.g. family farms or clinical practice); will enable patent holders to reap monopoly profits even from life saving therapies and diagnostic techniques; will lead us to objectify life and living creatures. human and otherwise.</p>	<p>+Patenting of life forms is justified on grounds of fairness to inventors and investors.</p> <p>- Ownership of life, or property rights in portions of the human genome, are inherently wrong.</p>
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<http://www.ic.gc.ca/eic/site/ppd-dppi.nsf/eng/ip00033.html>

## Scientists influence policy...

**When Patents Threaten Science**

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**Conclusion**  
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## Human gene patents – pro and contra

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**Arguments against human gene patents**

- harm the research environment (consequentialist)
- adversely effect public access to useful health care procedures (consequentialist based on public health benefit)
- lead to an inappropriate commodification of life (deontological)
- violate the principle against the ownership of human beings/human dignity (deontological)

**Arguments in favor of human gene patents**

- stimulate the development of new medicines/tests (consequentialist)
- are deserved by/the right of those who develop new applications/inventions

## Human gene patents – pro and contra

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**Australia**

- Landmark ruling that concluded that patents on naturally occurring DNA sequences are valid: in Feb 2013 a judge of the Federal Court of Australia ruled in favour of a Myriad Genetics patent on the BRCA1 gene. The ruling has been appealed to the Full Bench of the Federal Court.

**United States**

- A few months later, the U.S. Supreme Court declared the opposite. In the US, natural biological substances themselves are patentable (apart from any associated process or usage) if they are sufficiently "isolated" from their naturally occurring states. Examples are: patents on adrenaline, insulin, vitamin B<sub>12</sub>, and some genes. However, the June 2013 landmark ruling by the U.S. Supreme Court concluded that naturally occurring DNA sequences are not eligible for patents.

Corderoy, Amy (March 4, 2013). "BRCA1 gene patent ruling to be appealed". Sydney Morning Herald.  
Sharples, Andrew (2011-03-23). "Gene Patents in Europe Relatively Stable Despite Uncertainty in the U.S.". Genetic Engineering and Biotechnology News.

## Human gene patents – pro and contra

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**Europe**

- The Biotech Directive (European Union directive 98/44/EC) allows for the patenting of natural biological products, including gene sequences, as long as they are "isolated from [their] natural environment or produced by means of a technical process."
- The European Patent Office has ruled that European patents cannot be granted for processes that involve the destruction of human embryos.

Decision G2/06 of 25 November 2008, WARF/Stem Cells (OJ EPO 2009, 306). See also Decision T 2221/10 of 4 February 2014, Culturing stem cells/TECHNION.  
Sharples, Andrew (2011-03-23). "Gene Patents in Europe Relatively Stable Despite Uncertainty in the U.S.". Genetic Engineering and Biotechnology News.

## Final conclusion

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- Patents raise ethical issues linked to ownership (on which we diverge) and distribution (on which we also diverge).
- These issues have two levels:
  - Which values should we prioritize when values conflict, and can we prioritize more of them?
  - When we try to protect a value, does it work?
- We also diverge on whether we *ought* to pursue some patentable avenues of research.
  - These questions are not directly to patents, but they tend to get smuggled into the discussion.

Thanks for your attention

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