

Gene patents and genetic testing: policy issues

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Mission of the Joint Research Centre

The Mission of JRC is to help put EU policy-making onto a scientifically robust foundation by providing customer-driven scientific and technical support for the conception, development, implementation and monitoring of EU policies.

European Commission - JRC Structure



IRMM – Geel, Belgium

- Institute for Reference Materials and Measurements



IE – Petten, The Netherlands

- Institute for Energy



ITU – Karlsruhe, Germany

- Institute for Transuranium elements



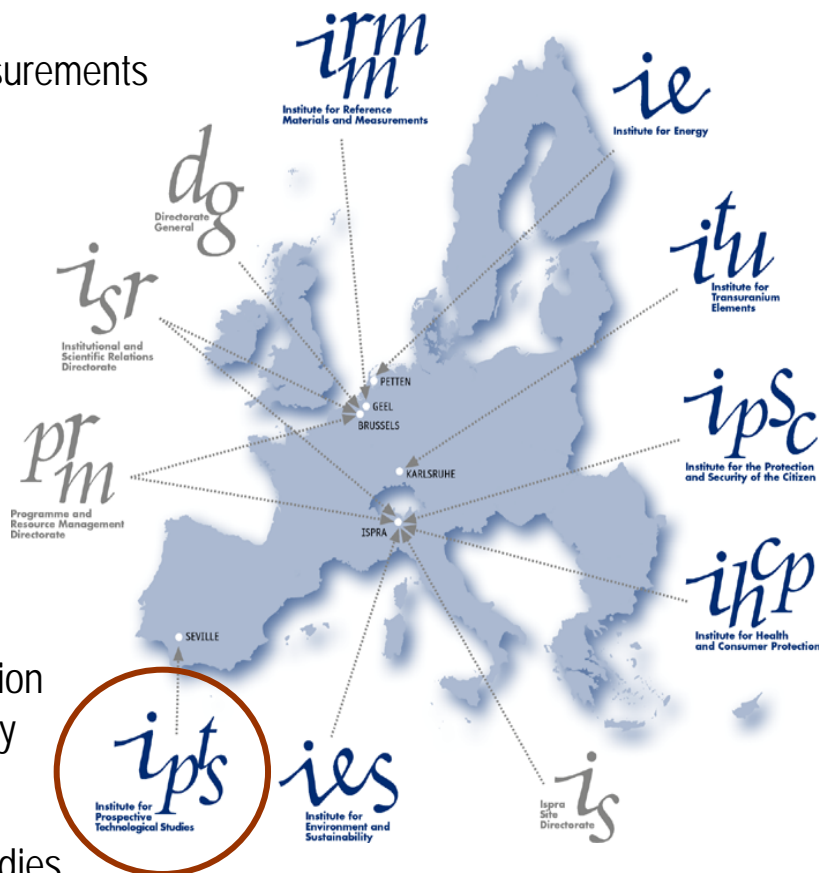
IPSC - IHCP - IES – Ispra, Italy

- Institute for the Protection and the Security of the Citizen
- Institute for Health and Consumer Protection
- Institute for Environment and Sustainability



IPTS – Seville, Spain

- Institute for Prospective Technological Studies



Total staff > 2600 people, IPTS > 200 people

IPTS mission

Within the JRC's overall customer-driven mission, that of the IPTS is:

to support the formulation of EU policies by researching science-based responses to policy challenges that have a socio-economic dimension as well as some scientific/technological connection.

IPTS and genetic testing

1. Quality Assurance and Genetic Testing in EU

(Ibarreta et al., 2004)

- Approval procedure for IVD does not generally involve clinical trials. Quality of genetic testing services seems to be a problem.
- A number of quality assurance schemes have been proposed, however the study found a low participation of laboratories in these schemes.

IPTS and genetic testing

2. Pharmacogenetics in EU (Zika et al., 2006)

Picture of the pharmacogenetic market

Main barriers to innovation and clinical uptake:

- Scarce and fragmented economic evidence
- Infrastructure: need for large-scale biobanks to validate results
- **Gene patents:** contrasting results

IPTS and genetic testing

3. Intellectual Property Rights and Genetic Testing

- Objective: to investigate, for the first time in Europe, possible impacts from DNA patenting in the field of diagnostics
- EU-wide survey of clinical laboratories and a series of case studies.
- Preliminary results in Hopkins et al. (2009)

DNA Patenting Concerns and Issues

- Legal Issues
- Economic Issues
- Research and Innovation issues
- Public Health Issues
- Ethical Issues

Directive 98/44/EC (*Biotech Directive*)

- Objective: harmonization and clarification in the field of biotechnology patents
- It requires EU Member States to recognise isolated genes and nucleotide sequences as patentable inventions. Recent rulings of the Board of Appeal of the European Patent Office have illustrated that patents can also be granted for methods of genetic testing without claiming genes themselves.

Evidence

Legal uncertainty (Huys et al, 2009)

- Low number of claims on genes *per se*
- Wide legal uncertainty as to the scope of the claims.
- Numerous method claims which tends to be blocking.
- Public and private joint patents especially in the US

Evidence

Danger and phantom menace

(Cook-Deegan et al., 2009; Hopkins et al., 2009)

- No pricing issues reported, so far. However, exclusive licensing could be a problem, especially in the US
- Unclear situation in Europe. Laboratories are not aware of patented technologies and do not use licences. Infringement is frequent but very low litigation. Low impact on price and on patient access.
- Patents does not seem to have a key role as a barrier in the development of DNA diagnostics.

Policy Challenges

- Assure patent enforcement in EU
- Provide legal support services (and / or training programs) for genetic testing labs. Establishment of a voluntary reporting system related to new/old patents and licences in the light of service provisions to patients
- Harmonising US, Japan and Europe patent approach

Policy Challenges

- Redefine "utility" concept; limiting the breadth of the claim and the subject matter
- Should exclusive licensing agreements be contrasted?
- Patent pools and/or clearing houses
- Public-private collaboration

Concluding Remarks

- EU - US differences
- New challenges will emerge as genomics knowledge progress
- How to account for ethical issues? Is the proposal of an Ethics Committee at the EPO an effective solution?
- More evidence and continue monitoring still needed.