



Technology transfer in the European Research Area

European Commission
DG Research - **HEALTH**

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HEALTH BIOTECHNOLOGY





Knowledge transfer

- Need to facilitate university-industry knowledge transfer (in particular to promote the exploitation of publicly-funded R&D results, and EU competitiveness); Europe is lagging behind the USA in this area
- Several relevant national initiatives in recent years :
 - Legislation changes (e.g. abolition of the « professor's privilege » in Germany, and other countries)
 - National guidelines (in France, Denmark, Ireland, etc.)
 - National model contracts (e.g. UK's « Lambert agreements »)
- ... usually with a purely national perspective → little coherence across Europe → obstacle for trans-national knowledge transfer



Knowledge transfer

- Need for a Community-level initiative – however while respecting the need for flexibility (national contexts)
- As announced several times, e.g. in the Communication “Putting knowledge into practice” (COM(2006)502) : “The Commission will present a **Communication** on improving **knowledge transfer** between the public research base and industry across Europe. This will provide guidance on how public authorities can address the main barriers which currently exist and how ownership and exploitation of R&D results and associated intellectual property rights can be best combined with the fundamental missions of public research organisations.”



Commission Communication & Guidelines

- The Commission adopted on April 4, 2007 :
 - A Commission Communication offering policy orientations to Member States (COM(2007)182) :
Improving knowledge transfer between research institutions and industry across Europe : embracing open innovation
 - Implementing the Lisbon agenda –
 - ... accompanied by a Commission Staff Working Document containing operational guidelines for universities and other PROs (SEC(2007)449)
- These documents were developed on the basis of many existing materials / initiatives + a public consultation (2006)



Main orientations offered in the Communication (1/2)

The Communication highlights the need :

- for research institutions to have sufficient **autonomy** to recruit experienced knowledge transfer staff on a competitive basis;
- for Member States to promote **pooling of resources** between those research institutions that do not have the scope and volume of exploitable research results to justify the establishment of a knowledge transfer office;
- for Member States to promote the development and delivery of **tools** to facilitate collaboration between research institutions and industry (e.g. model contracts);
- to revisit the question of a single European **ownership model** for publicly funded research;



Main orientations offered in the Communication (2/2)

- for **appraisal criteria** for researchers to also take into account activities such as patenting, licensing, and collaboration with industry, in addition to academic criteria such as publications and prizes;
- for Member States to not only use grants but also other **funding mechanisms** at their disposal to help promote knowledge transfer activities, e.g. R&D tax credits or public procurement targeting innovative solutions;
- for better **benchmarking** “innovation-related activities”, which, if conducted on the basis of comparable metrics across the EU, would allow research institutions to compare their own achievements at European as well as at national level;
- for Member States to encourage and facilitate the introduction of **full cost accounting** in research institutions.



Guidelines

1. Introduction

2. **Balancing the benefits**

Benefits to research institutions ; Benefits to society ; The balance between openness and exploitation of results

3. **Guidelines**

3.1. Policy Issues for Heads of Research Departments / Faculties
Intellectual Property (IP) Policy ; Incentives policy ; Conflicts of interest policy ; Knowledge Transfer resources

3.2. Good practices regarding contractual arrangements for research between research institutions and industry

The need for openness ; Beginning negotiations ; Who should be involved ; The distribution of rights between the parties ; Research institutions should publish the results of research projects ; Confidentiality ; IP enforcement ; Relationship management and dealing with disagreements ; Governing law ; State aid rules



Towards a European KT framework

- “The analysis and policy orientations set out in this Communication constitute a starting point for discussions on a common European framework for knowledge transfer in order to create a level playing field and a more coherent European landscape for knowledge transfer.”
- Knowledge transfer/sharing is one of the 6 axes of the recent **ERA Green Paper** (COM(2007)161), which « *raises a number of questions on how to deepen and widen the European Research Area so that it fully contributes to the renewed Lisbon strategy. It intends to launch a wide institutional and public debate with a view to preparing initiatives for 2008.* » (including on-going public consultation)



General IPR issues

- « **Patent strategy** » communication adopted in April 2007 (COM(2007)165), focusing mainly on :
 - Relaunching the Community patent
 - Improving the European patent system (EPLA, London Protocol)
- « **IPR strategy** » being prepared, including :
 - « Flanking measures » : awareness & training, support to SMEs, alternative dispute resolution mechanisms, patent litigation insurance, ...
 - Possibly certain R&D-specific IPR issues (grace period, research exemption, etc.)



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Int. Herald Tribune

VIEWS | EDITORIALS & COMMENTARY

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IPR

Who owns your genes? ■ By Michael Crichton

Patenting life

You, or someone you love, may die because of a gene patent that should never have been granted in the first place. Sound far-fetched? Unfortunately, it's only too real.

In the United States, gene patents are now used to halt research, prevent medical testing and keep vital information from you and your doctors. Gene patents slow the pace of medical advance on deadly diseases. And they raise costs exorbitantly: A test for breast cancer that could be done for \$1,000 now costs \$3,000.

Why? Because the holder of the gene patent can charge whatever he wants, and does. Couldn't somebody make a cheaper test? Sure, but the patent holder blocks any competitor's test. He owns the gene. Nobody else can test for it. In fact, you can't even donate their own breast cancer gene to another scientist without permission. The gene may exist in your body, but it's now viewed as private property.

This bizarre situation has come to pass because of a mistake by an underfinanced and understaffed government agency. The United States Patent Office misinterpreted previous Supreme Court rulings and some years ago began — to the surprise of everyone, including scientists decoding the genome — to issue patents on genes.

Humans share mostly the same genes. The same genes are found in other animals as well. Our genetic makeup represents the common heritage of all life on earth. You can't patent snow, eagles or gravity, and you shouldn't be able to patent genes, either. Yet by now one-fifth of the genes in your body are privately owned.

The results have been disastrous. Ordinarily, we imagine patents promote innovation, but that's because most patents are granted for human inventions. Genes aren't human inventions, they are features of the natural world. As a result these patents can be used to block innovation, and hurt patient care.

For example, Canavan disease is an inherited disorder that affects children starting at 3 months; they cannot crawl or walk, they suffer seizures and eventually become paralyzed and die by adolescence. Formerly there was no test to tell parents if they were at risk. Families enduring the heartbreak of caring for these children engaged a researcher to identify the gene and produce a test. Canavan families around the world donated tissue and money to help this cause.

When the gene was identified in 1993, the families got the commitment of a New York hospital to offer a free test to anyone who wanted it. But the researcher's employer, Miami Children's Hospital Research Institute, patented the gene and refused to allow any health care provider to offer the test without paying a royalty. The parents did not believe genes should be patented and so did not put their names on the patent. Consequently, they had no control over the outcome.

In addition, a gene's owner can in some instances also own the mutations of that gene, and these mutations can be markers for disease. Countries that don't have gene patents actually offer better gene testing than the United States, because when multiple labs are allowed to do testing, more mutations are discovered, leading to higher-quality tests.

Apologists for gene patents argue that the issue is a tempest in a teapot, that patent licenses are readily available at minimal cost. That's simply untrue. The owner of the genome for Hepatitis C is paid millions by researchers to study this disease. Not surprisingly, many other researchers choose to study something less expensive.

But forget the costs: Why should people or companies own a disease in the first place? They didn't invent it. Yet today, more than 20 human pathogens are privately owned,



Raymond Verdaguer

including haemophilus influenza and Hepatitis C. And we've already mentioned that tests for the BRCA genes for breast cancer cost \$3,000. Oh, one more thing: If you undergo the test, the company that owns the patent on the gene can keep your tissue and do research on it without asking your permission.

Don't like it? Too bad.

The plain truth is that gene patents aren't benign and never will be. When SARS was spreading across the globe, medical researchers hesitated to study it — because of patent concerns. There is no clearer indication that gene patents block innovation, inhibit research and put us all at risk.

Even your doctor can't get relevant information. An asthma medication only works in certain patients. Yet its manufacturer has squelched efforts by others to develop genetic tests that would determine on whom it will and will not work.

Such commercial considerations interfere with a great dream. For years we've been promised the coming era of personalized medicine — medicine suited to our particular body makeup. Gene patents destroy that dream.

Fortunately, two U.S. congressmen want to make the full benefit of the decoded genome available to all Americans. Last Friday, Xavier Becerra, a Democrat of California, and Dave Weldon, a Republican of Florida, sponsored the Genomic Research and Accessibility Act, to ban the practice of patenting genes found in nature. Becerra has been careful to say the bill does not hamper invention, but rather promotes it. He's right. This bill will fuel innovation, and return our common genetic heritage to us. It deserves our support.

Michael Crichton is the author, most recently, of the novel "Next."

**Gene patents
slow the pace of
medical advance on
deadly diseases.**



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Clinical trials...



European collaboration:

- Patients...



FP6 Specific Support Actions funded by the Health Theme

- **Training of young ScanBalt LSH Scientists in project and Innovation management and economic exploitation (TRAYSS PRIME)** provides scientific training, project management and technology transfer training in the Baltic Sea Region.
- **Bioentrepreneur Boot Camps**, an FP6 EU-funded project (2007-2008), provides **training** specifically supporting Scientists to prepare viable **business plans** and launch successful new Biotech Companies, with special attention to new members and candidates countries.
- **Intellectual Property Rights and asset management courses (IPRAM)**, an FP6 EU-funded project (2007-2008), organises trainings about essential aspects of IPR in the field of life sciences and biotechnology to young scientists at universities across the Europe.



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Council of European BioRegions (CEBR) – Networking Europe's biocommunities

CEBR is a network of organisations that support their local bio community through direct services including networking, incubation, partnering and cluster promotion. It is the first network of its kind to bring together such organisations and Members will develop and implement new biotech support activities across Europe. Its mission is to build a competitive European biotechnology sector on the world stage through:

- Reduction of biotech fragmentation in Europe
- Creation of a level playing field for companies across Europe
- Transforming competitiveness to cooperation between regions
- Creation of a platform for EU-wide initiatives and services

CEBR is driven by the needs of industrial biotechnology in Europe and brings a new vision to a traditionally academic-driven process



Financing – tax incentives

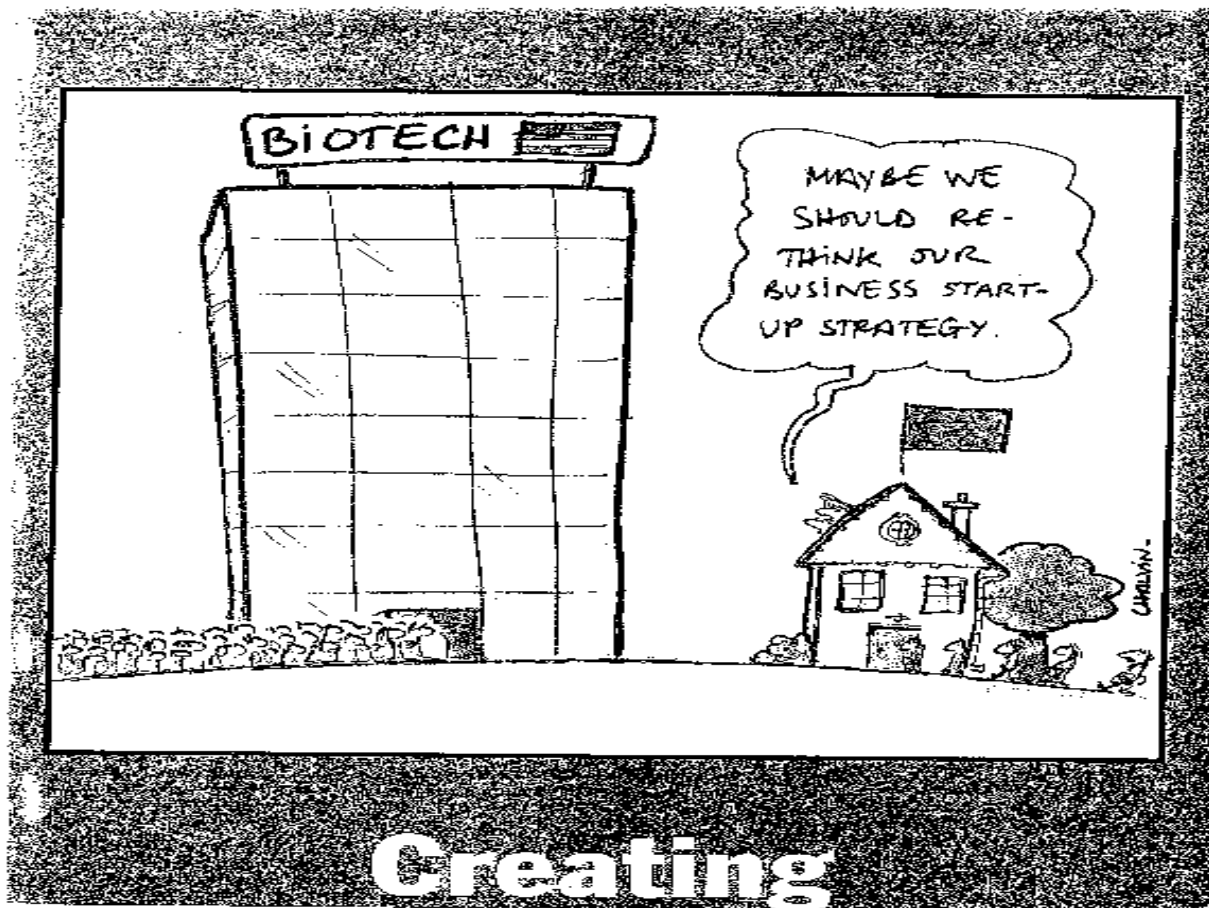
- Young innovative company (YIC)
- Realisation of Young Innovative Company Status, YIC, for biotech companies
- Partnership: Sweden, Estonia, Finland, Norway, France



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Entrepreneurship



Creating your own company

Aided by positive governmental policies and prudent venture capitalists, a significant number of biotech companies are at last setting up in Europe. Do these successes really make a difference?

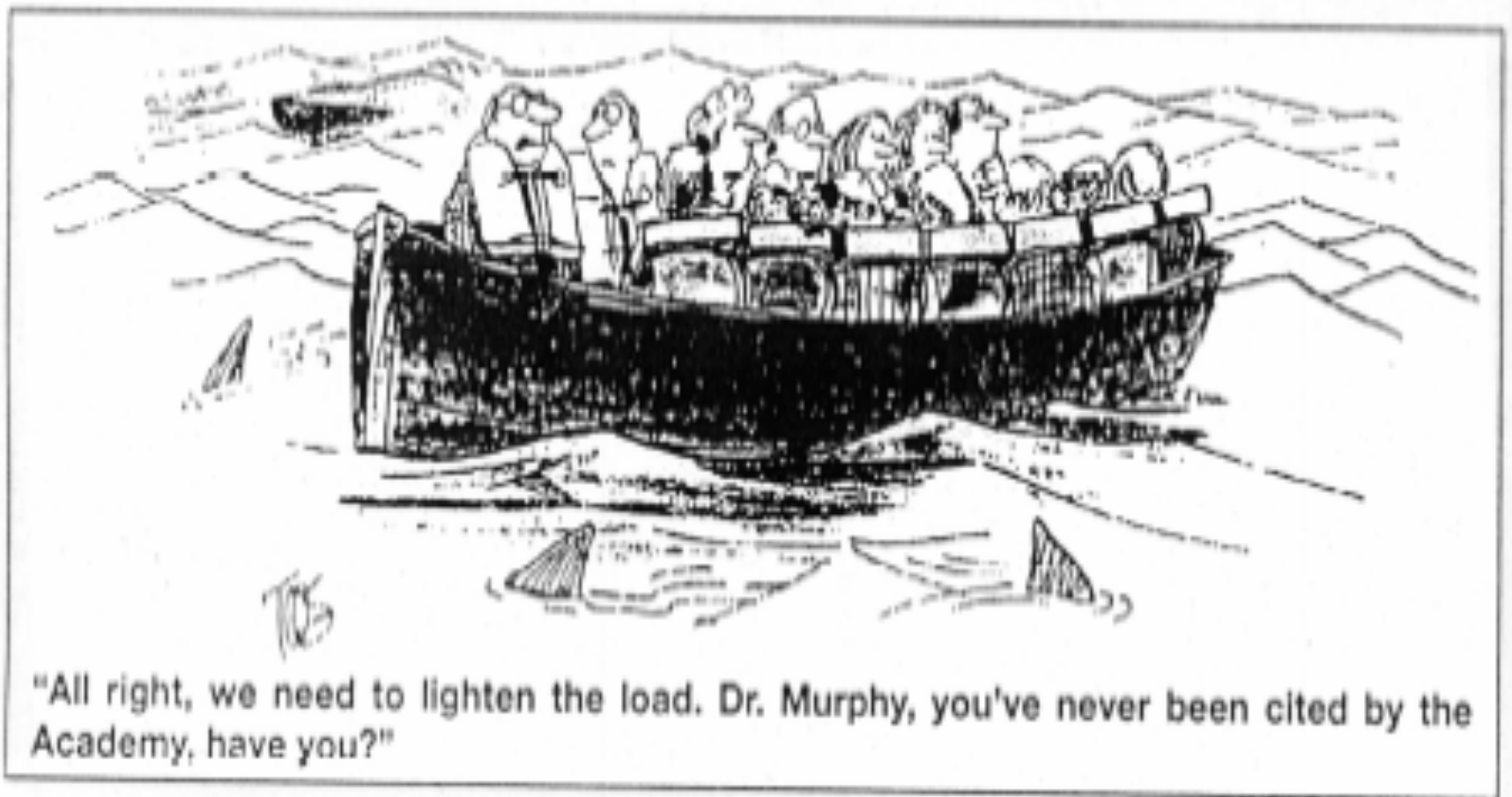
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Education

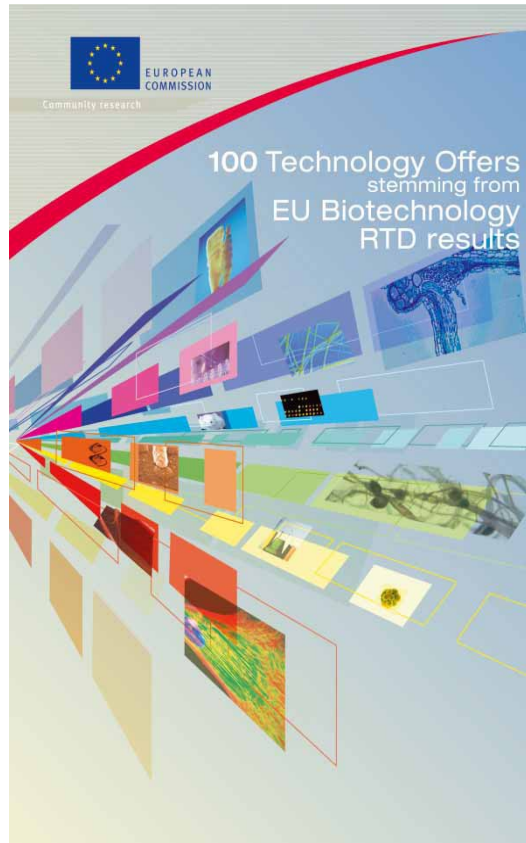




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Technology offers



<http://www.cordis.lu/lifescihealth/home.html>



Citations ...

- “Protectionism slows down EU innovation”
- “Private sector spending in R&D will require significant changes in Europe's business environment”
- “We need to go beyond simple quantitative targets and move towards a more efficient business environment for innovation”
- “Regional policy comes before Science policy”



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**Research turns money into
knowledge –
Innovation turns knowledge
into money**

(a wiseguy)



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Thank you for your attention!



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