

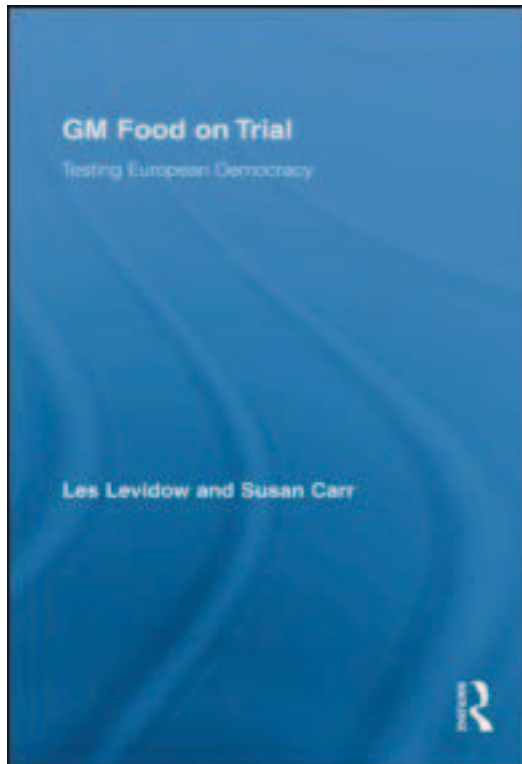
# Patents & Risk Research

## Access to Material, Corporate Control & Independent Science

**Advancing the Understanding of Biosafety 2012**

**Hartmut Meyer (ENSER, Scientific Coordinator)**

# Genetic Engineering Testing Democratic Legitimacy



Genetic engineering became the crystallisation point for fierce debates on corporate control over research, seeds and food.

„GM food evolved as a metaphor for larger questions about democratic legitimacy ... the democratic deficit that it has revealed.“

Prof. Frank Fischer, Rutgers University

# Genetic Engineering Corporate Control Through Patents



- Intellectual property rights, specifically patents
- Every WTO Member is forced to allow for patenting of transgenic organisms (GMOs)
- TRIPS 27. 3(b): Members may also exclude from patentability ... essentially biological processes for the production of plants or animals **other than non-biological and microbiological processes.**

# Crop Scientists Say Biotechnology Seed Companies Are Thwarting Research



Craig Lassig for The New York Times

Ken Ostlie, an entomologist, said Syngenta had withdrawn its permission and a study about corn and rootworms had to stop.

“Biotechnology companies are keeping university scientists from fully researching the effectiveness and environmental impact of the industry’s genetically modified crops, according to an unusual complaint issued by a group of those scientists.”

Andrew Pollack, New York Times, February 19, 2009  
<http://www.nytimes.com/2009/02/20/business/20crop.htm>

# Do Seed Companies Control GM Crop Research?

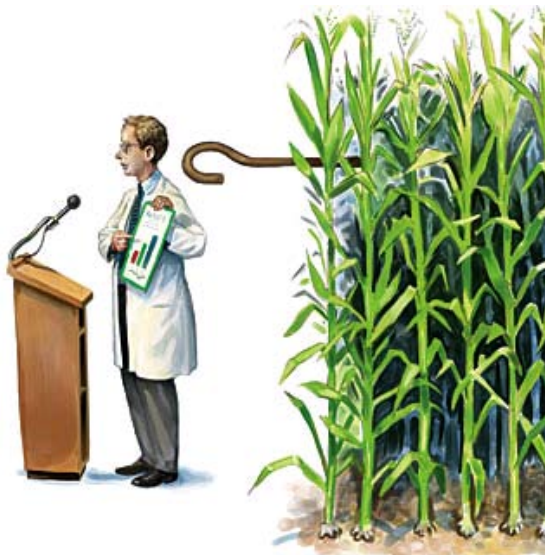


Image: Matt Collins

„Scientists must ask corporations for permission before publishing independent research on genetically modified crops. That restriction must end“

Editorial, Scientific American, August 13, 2010  
<http://www.scientificamerican.com/article.cfm?id=do-seed-companies-control-gm-crop-research>

# Do Seed Companies Control GM Crop Research?



“For a decade their **user agreements have explicitly forbidden the use of the seeds for any independent research**. Under the threat of litigation, scientists cannot test a seed to explore the different conditions under which it thrives or fails. They cannot compare seeds from one company against those from another company. And **perhaps most important, they cannot examine whether the genetically modified crops lead to unintended environmental side effects**.

Research on genetically modified seeds is still published, of course. But **only studies that the seed companies have approved ever see the light of a peer-reviewed journal**. In a number of cases, **experiments** that had the implicit go-ahead from the seed company **were later blocked from publication because the results were not flattering.**”

# Answer of U.S. Biotech Companies



## **Research with Commercially Available Seed Products**

To enable the public sector research community to independently conduct research studies on commercially available seed products in laboratory, greenhouse, and field settings for the purpose of understanding the technology, education, extension and the safe and effective use of these products.

# Answer of U.S. Biotech Companies



To assure that the public sector research community is free to design robust, scientifically sound experimental protocols and methodologies, and to derive independent conclusions.

To encourage and assure that the public sector research community is free to publish findings in peer reviewed scientific or research journals, with reasonable notice to companies.

*American Seed Trade Association's Executive Committee, Sept. 17, 2009*  
*Biotechnology Industry Organization's Food & Agriculture Section Governing Board, Sept. 10, 2009*

[http://www.amseed.com/pdfs/Research\\_CommSeedProducts.pdf](http://www.amseed.com/pdfs/Research_CommSeedProducts.pdf)



# Remarks of ENSSER



- The U.S. patent law still allows massive research restrictions
- The statement does not bind patent holders
- The statement only includes crop seeds that are freely available on the market
- Independent research on crops under development is still not possible
- Data for risk assessment are fully under control of patent holders

# How about the Situation in Europe?



- European patent law contains a "research exemption"
- Widely applied in drug regulatory research
- Unknown amongst biosafety scientists
- What are the implications of the "research exemption" for risk research with patented seeds and plants?
- Legal opinion by Prof. Dr. Dr. Dolder, University of Basel, Switzerland

# TRIPS Art 30: Exceptions to Rights Conferred



**Members may provide limited exceptions to the exclusive rights conferred by a patent,** provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

(of 1994)

# Convention for the European Patent for the common market



## **Art 27: Limitation of the effects of the Community patent**

The rights conferred by a Community patent shall not extend to

[...]

(b) acts done for experimental purposes relating to the subject-matter of the patented invention;

(of 1975)

# Proposal for a regulation ... implementing enhanced



## cooperation in the area of the creation of unitary patent protection

### Art 8: Limitation of the effects of the European patent with unitary effect

The rights conferred by the European patent with unitary effect shall not extend to any of the following:

(b) acts done for experimental purposes relating to the subject matter of the patented invention;

# Legal Opinion on Seed Patents and Research Exemptions



Type of research	Patent claims: substance / seed	Patent claims: process of production	Patent claims: use e.g. in agriculture
risks to human & animal health and environment	<b>exempted</b>	exemption doubtful	<b>exempted</b>
delaying development of resistance in weeds or insects	<b>exempted</b>	exemption doubtful	exemption doubtful
improvements of yields and agricultural practices	exemption doubtful	<b>not exempted</b>	<b>not exempted</b>

# Legal Opinion on Seed Patents and Research Exemptions



## **Research exemption as an independent legal instrument**

The research exemption of patent law cannot grant access to GM material that otherwise would not have been accessible. Research exemption does not constitute an independent legal basis for free research on GM seeds or free access to GM seeds in general. Research exemption can only exempt and protect research on legally obtained GM material.

# Next Steps



- Engage in the current debate in the EU on biotechnology patents
- Prepare workshop and materials for parliamentarians
- Make the issue known amongst research communities outside of the medical field