Intellectual Property Rights and Research Restriction

Hartmut Meyer, ENSSER

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Introduction

After 15 years of GE crop commercialisation a new dimension was added to the controversy about appropriate methodological approaches and interpretations in the fields of risk research and risk management. In February 2009, the New York Times featured a story reporting about a complaint of 26 leading U.S. entomologists working in GE crop risk research and evaluation. The statement at the U.S. EPA web page reads as follows:

> *The following statement has been submitted by 26 leading corn insect scientists working at public research institutions located in 16 corn producing states. All of the scientists have been active participants of the Regional Research Projects NCCC-46 "Development, Optimization, and Delivery of Management Strategies for Corn Rootworms and Other Below-ground Insect Pests of Maize" and/or related projects with corn insect pests. The statement may be applicable to all EPA decisions on PIPs, not just for the current SAP. It should not be interpreted that the actions and opinions of these 26 scientists represent those of the entire group of scientists participating in NCCC-46. The names of the scientists have been withheld from the public docket because virtually all of us require cooperation from industry at some level to conduct our research.*
>
> *"Technology/stewardship agreements required for the purchase of genetically modified seed explicitly prohibit research. These agreements inhibit public scientists from pursuing their mandated role on behalf of the public good unless the research is approved by industry. As a result of restricted access, no truly independent research can be legally conducted on many critical questions regarding the technology, its performance, its management implications, IRM, and its interactions with insect biology. Consequently, data flowing to an EPA Scientific Advisory Panel from the public sector is unduly limited."*

The statement finally made public what since many years had been known to scientists in the field: those whose products shall be scrutinised for negative effects can determine who is conducting this research, how the research is done and what can be published. The agro-biotechnology industry claims that the IPR laws give them the right to do so. The letter and subsequent media reports put the U.S. biotechnology industry under pressure and resulted in the adoption of a Position Statement that enlarged the free use of patented commercialised seeds beyond purely agricultural reseach issues. The September 2009 document "Research with Commercially Available Seed Products" suggests that patent owner also should allow free research on pest resistance and environmental biosafety issues.

While this agreement was propagated as major commitment by the biotechnology industry it has to be stressed that it is only a recommendation and that based on the current U.S.-IPR laws, patent owners are entitled to forbid any biosafety research with patented GM seeds that are available on the market! Still and most important, biosafety research on patented NOT-commercialised GMOs is not an element of the recommendation, researchers need the consent of and need to enter into an agreement with the patent owner.

IPR Background

The fundamental requirements of independent research are free access to material, free choice of concepts and methodologies, and free choice of how and where to publish the results. Tangible property laws require that scientists have to receive an access permission if the material they want to analyse is under private ownership. If the material is available as commodity in the market, the purchase renders the ownership to the buyer, in this case the scientist. In general, the first owner of the physical material does not have legal rights to determine the use of the material by the next owner.

This is different when the potential research material is in addition covered by rights on intellectual property. The current intellectual property rights (IPR) as patents or plant variety protection based on the WTO TRIPs-Agreement or the UPOV 1991 Convention empower the first owners of the IPR to decide about the future use of the material by the new user. According the patent laws, the owner of a patent is not the inventor but the applicant of the patent, in general a private company or in some cases a public institution.

Due to the pressure of industrialised countries and their IPR-intensive industries and contrary to older international IPR treaties, the TRIPs-Agreement of the WTO obliges its members to grant IPR in the sectors health, food and agriculture. Developing countries could secure during the negotiations that WTO members can exclude animals and plants as well as essentially biological breeding methods from patentability. In the case of plants, WTO members must secure effective sui generis protection if they ot the patent on plants. Proponents of industrial IPR advocate the 1991 UPOV Treaty on plant breeder rights as the only appropriate sui generis regimes.

Article 30 of the TRIPs agreement allows its members to give limited exemptions to the exclusive rights conferred by a patent.[1] The EU Community Patent Convention specifies the circumstances for such exemptions and grants a far-reaching "research exemption" as far as the research relates to the subject matter of the invention.[2] The patent laws of almost all EU have implemented this provision. The Community Patent Convention is currently under revision; the recent draft still contains this exemption.[3] However, for laypersons it is not obvious from the legal text if this research exemption would also cover experiments with the invention on risk issues, eg. GMO biosafety research, which might not be covered by the subject-matter of the invention. Recital 14 of the preamble of the EU bio-patent directive recommends that such exemptions in the field of biotechnology must be possible "notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards"[4].

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1 TRIPS Art 30 *Article 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.

2 Convention for the European Patent for the common market
Article 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;

3 more information: http://www.epo.org/patents/law/legislative-initiatives/community-patent.html
2009 Proposal for a Council Regulation on the Community patent
Article 9 Limitation of the effects of the EU patent
The rights conferred by the EU patent shall not extend to:
(b) acts done for experimental purposes relating to the subject-matter of the patented invention;

4 Directive 98/44 on the legal protection of biotechnological inventions
Preamble Recital (14) Whereas a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes; whereas, consequently, substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards;

Research exemption and biosafety research

One prominent issue right in the centre of ENSSER's work and concerns is the (mis)use of Intellectual Property Rights (IPR), specifically patents, to restrict access to biological material and organisms necessary to conduct research for risk assessment independent from the interests and influence of the IPR holder. These restrictions in many cases come together with giving preferential access to the necessary materials and organisms to research groups that follow the research concepts of the IPR holders and accept their conditions on interpretation and publication of data. While in the field of pharmaceuticals, the research exemption contained in the patent laws of many states as the EU are used routinely by independent research groups, this possibility is not commonly known in the circles undertaking research on environmental and health risks of other patented material as GM seeds. It is unclear to many researchers whether the use of approved GM plants which are available on the seed market for independent risk research is legal with respect to the current provisions of the patent and seed variety laws or if approval for such research need to be sought from the IPR holders. Access to GM seeds for pre-approval risk research is seen as impossible by many groups although the research exemption would also apply for those seeds if they are covered by IP-protection. The need to run control experiments with the non-GM parental lines which might neither be under IP-protection nor available on the market constitutes the strongest impediment for independent research. In this situation, ENSSER asked for a legal opinion to clarify the legal situation in the EU and to inform research groups about their legal possibilities to gain access to the different categories of GM seeds.

Summary of the Legal Opinion

1) European patent law grants a "research exemption"

The Convention on the EU Community Patent of 1975 (the so-called Luxembourg Convention) introduced an explicit provision on the research exemption, which functioned as a model provision for all subsequent national regulations of the EU member states:

> Article 31 Limitation of the effects of the Community patent
>
> The rights conferred by a community patent shall not extend to:
>
> (a) acts done privately and for non-commercial purposes;
>
> ***(b) acts done for experimental purposes relating to the subject-matter of the patented invention; (....)***

A similar provision for research exemptions was introduced in the 1991 text of the Plant Varieties Convention (UPOV 1991) and subsequently signatories to this convention started to introduce similar regulations in their national statutes. The linkage ***"relating to the subject-matter of the patented invention"*** was drafted intentionally in an imprecise and non-technical way, and therefore constituted almost a catch-all category.

2) Research <u>on</u> the patented subject matter versus research <u>with</u> the patented subject matter

The linkage between the subject matter of a patent and research activities was argued and interpreted in a differentiating way in only two decisions of the German Federal Court. The court distinguished between research ***on the object*** (subject matter, technical teaching) of a patent and those research activities making use of the teaching of a patent ***as an instru-***

ment for obtaining new knowledge. The former shall be covered by the research exemption; the latter shall fall under the scope of protection of the patent and hence be prohibited. Considering the usual types of patent claims in seed patents, as well as the type of research to be exempted or privileged, the following is an illustration of **on/with-typology** for evaluating a particular case

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	exempted	exemption doubtful	exempted
delaying development of resistance in weeds or insects	exempted	exemption doubtful	exemption doubtful
improvements of yields and agricultural practices	exemption doubtful	not exempted	not exempted

3) Specific issues for research on GM plant risks

a) Access to IP-protected marketed seeds

It should not be difficult for independent researchers in the EU member states to obtain access to marketed GM seeds, e.g. MON810, in sufficient quantities and in a legally not objectionable way by means of purchasing contracts and hence to become lawful owners of the GM material without legal restrictions. Contractual obligations in „stewardship agreements“ *not* to transfer these GM seeds to third parties will usually constitute „vertical agreements and concerted practices“ under Commission Regulation (EU) No 330/2010 and hence be invalid. If accused to infringe patents of the GM producer, the researcher may not only invoke the research exemption, but can also pretend that patent protection with regard to the GM material in question is at this stage already *exhausted* as a result of lawful introduction to the market.

b) Access to IP-protected seeds not yet approved for marketing

On the basis of the powers granted in administrative, e.g. environmental law, the state as represented by its organs is entitled to procure samples of GM material / organisms and to enforce access to such GM organisms even without the consent or against the explicit will of the owner, and to use the forces of the law to do so. Since this power of the state administration is intended to facilitate prevention of abuse and control of risk, the right to access and procurement should include the right to examine and investigate the GM material with a view to minimising risk. As an example, the German Biotechnology Act of 1990/2008 explicitly provides for the right of the state administration to seize samples for investigations.

It seems, however, extremely doubtful whether, invoking this instrument of compulsory licensing, external researchers in the field of GM seeds will ever be granted access to GM seeds without the consent or against the explicit will of the producer of GM seeds and holder

of the IP rights. It is extremely unlikely that in the field of GM seed patents, the statutory requirements for such a compulsory licensing will ever be met.

In order to gain access to such material, e.g. SmartStax maize, independent researchers can refer to the research exemption but in any case need to enter an agreement with the patent holder specifying the details and aims of the intended research.

c) Access to seeds not protected by IPR and not marketed

To conduct scientifically sound risk research, the appropriate non-GM comparators, e.g. the parental varieties or breeding lines, need to be assessed in parallel to the GM plant. While is some cases the parents are commercial varieties in others they could be breeding lines not covered by any IPR (e.g. the non-GM parent of SmartStax maize is the breeding line XE6001, itself a hybrid between the lines HCL301 of Monsanto and 5XH751 of Dow AgroSciences). The research exemption does not apply to such material, access to this category will, as a general rule, not be granted to independent researchers by the owner(s).

Conclusions

Access to marketed IP-protected GM seeds should be free for independent researchers, any restrictions seem to contradict EU law. If the IP-protected GM seeds are not marketed yet, independent researchers can refer to the research exemption but need to conclude a contractual agreement with the IP-holder to gain access. The conditions in this contract should not interfere with scientific issues as selecting methodologies, interpreting and publishing results. The owners of those experimental, parental lines that are necessary for independent researchers as non-GM controls but are not IP-protected are under no obligations to grant access to these seeds. To enable independent and sound risk research, access to the appropriate non-GM comparators needs to be made possible by specific legal provisions, e.g. in the EU GMO law.