



CropBooster-P

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CropBooster-P principles for IPR establishment and Socially Responsible Licensing

Introduction

CropBooster-P's goal is to pave the ground for future research that will lead to improved crop yields, increased sustainability and reduced environmental impact, and guaranteed nutritional quality of food. Plant breeding is instrumental in producing desired plant types with improved characteristics ("traits") useful to society. Breeders have the general goal to create new genetic diversity in a plant to obtain an improved phenotype. Over the last decades the focus of breeding companies has shifted from a more general, overall improvement of plants to the development and improvement of specific traits.

Without plant breeding no new varieties would be developed. Breeding of a new variety or the development of a new characteristic can take 10 or more years. The related investments can be quite high, especially for the development of a new trait by the screening of hundreds to thousands of wild species or crop relatives ("pre-breeding") or modern biotechnology (e.g., mutagenesis). Even for traits which are not considered to be genetically modified, the investment can increase beyond 10 million Euro. Since plants can be easily propagated by farmers or competitive breeders, such an investment can only be justified if breeding companies can obtain an adequate return on investment. This is ensured by society through the grant of a time limited "exclusivity" by the use of intellectual property rights (IPRs).

Breeding is crucially dependent on access to biological material (or: germplasm) which is the key source of genetic variation. Without biological material breeders cannot develop new varieties and breeding induced innovation would stagnate. This requirement differentiates the plant breeding area from all other areas of technology and requires a careful balancing of intellectual property protection and access rights. Historically, plant breeders rights (PBRs) were the prevailing form of IP protection for vegetable breeders. Under the PBRs regime the "breeders' exemption" ensures that the legally available biological material of protected varieties can be used to breed new varieties. These new varieties can in general be commercialized without authorization from the PBR owner.



Therefore, the best properties of new varieties are available to the breeding programs of every actor in this area thereby stimulating innovation and competition.

Currently patents on plant related innovations – especially new traits – are gaining importance. This has changed the situation for plant breeders who traditionally under PBRs were allowed for unimpeded breeding activities, i.e. without the need for a license from the right holder. There has been increasing discussion about patents on vegetable plant traits over the past years, especially in Europe. Proponents of such patents claim that they foster innovation, knowledge-sharing and continued investments in research and development. Opponents argue that such patents are unnecessary because of the intellectual property protection offered by plant breeders' rights and that patents impede the work of breeders because they can no longer gain access to biological materials, or can do so only after a delay or at a high cost. This debate is so relevant for breeding companies that eleven companies have worked together to establish the International Licensing Platform Vegetable (<https://www.ilp-vegetable.org>) with the aim to provide plant breeders around the world with faster, more efficient and cost effective, guaranteed access to crucial vegetable plant traits that are currently covered by patent claims by ILP member companies.

For the above mentioned reasons we advocate, also in the framework of CropBooster-P's goal of a future crop-yield improvement programme (**the FCYIP**), for global-access policies that promote an increased awareness and use of socially responsible licensing (SRL) principles, which is the practice of licensing IPR in a way that is considerate to global needs. In practice, SRL includes sets of terms that promote access to innovation (see par. 3). Such terms may include non-exclusive licensing of technologies with differential access or pricing for developing countries; a liberal reservation of rights for further non-commercial research by the originating public research organisations; and the return of benefits (not necessarily monetary) to countries that contribute resources or expertise to the research. This is most forcefully captured under the “access and benefit-sharing for genetic resources” provisions in the Convention on Biological Diversity (United Nations, “Convention on biological diversity” (1992); available at www.cbd.int/doc/legal/cbd-en.pdf) and the accompanying Nagoya Protocol on ‘Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity’ ((2010; available at www.cbd.int/abs/), which came into force in October 2014.



Proposed knowledge transfer strategy and governance

The execution of the roadmap that CropBooster-P will deliver will require a large-scale, European wide research effort involving scientist from academia and from industry from a large number of scientific disciplines. The general strategy model of CropBooster-P for the utilization of its research outcomes will therefore be based on public-private partnerships bringing closer Europe's strategic and applied plant science communities and will create economic opportunities for our bio-economy at all levels of its operation.

Through the direct participation of companies and other stakeholders in the research program, the aim of the FCYIP will be to combine scientific excellence with innovative impact and, therefore, to transfer new knowledge to users to realize the previously mentioned societal benefits. The FCYIP model of valorisation will be similar to the so-called built-in valorisation model: i.e. bringing private parties together with public research institutes up front, agreeing about the rights and fees to use research results as well as the sharing of research strategy and costs. This model is followed by many large-scale EU research programmes and long standing PPPs at national level.

The main objective of the FCYIP research efforts will be mainly addressed at developing pre-competitive know-how. The goals of the subsequent knowledge transfer activities and initiatives that the partners in FCYIP will deploy are geared at the conversion of their know-how into successful innovations. The specific goals of the valorisation activities should then focus on:

- defining clear and pre-defined strategies and rules regarding intellectual property (IP) and publication of results allowing open innovation and global-access policies
- increasing awareness for IP issues and value of knowledge amongst the FCYIP academic participants
- supporting and coaching from idea to IP, technology platform and/or spin-off
- implement IP protection strategies fostering open innovation and socially responsible licensing
- increasing awareness of scientists of the business aspects of participating companies and of the societal implications of their research.



We foresee that for governance simplicity, the participants in the collaborative efforts most probably will avoid to set up a legal entity and thus the resulting governing body will not own any IP itself, but IP ownership will be vested at the public research organisation who generates it. Many if not all public research organisation partnering the FCYIP consortium have a track record in knowledge transfer and IP commercialization with specific technology transfer bodies, located in one or more units or corporate departments, indicated here as TTO. On this basis, a best option would be to nominate one responsible for coordination within the collaborative efforts, e.g. a Valorisation Manager playing a pivotal role by co-operating with all those responsible for knowledge transfer at the public research organisations TTO's in identifying and managing intellectual assets derived from the FCYIP research activities. This includes protecting intellectual property and transferring or licensing rights to other parties. The Valorisation Manager main task should be addressed at supporting the public partners in FCYIP in identifying, acquiring and managing their own IP resulting from a specific research program. The Valorisation Manager should be anchored at the level of consortium Management Team to ensure that valorisation of results is an integral part of the mission.

The knowledge transfer process should be started as soon as IPR is established, e.g. a patent is filed, by offering the IPR to the industrial partners in the collaborative program for evaluation. They might then make use of a Right of First Negotiation within a defined period of time. In case of no interest by the industrial partners, the relevant TTO can offer the invention to third parties in the name of the public research organizations, always in line with socially responsible licensing principles.

Proposed set of terms for Social Responsible Licensing

Given the ambitions and task of CropBooster-P to increase the societal impact of research and innovation, public research organisations have an ethical obligation to the publics they serve and a responsibility to comply with their self-declared mission statements, one of which is service to the wider community through the pursuit and dissemination of knowledge. Concomitantly, efforts are required also toward global-access licensing policies. The roadmap of CropBooster-P will concern a complex public-private partnership with potentially huge societal and economic interests. Key is how the parties can best deal with the tension between science, commerce and society, and how can



a climate of transparency be promoted. Socially responsible licensing means that account needs to be taken of the effective availability of the products or services to be developed based on the licensed knowledge. The principles formulated in this document are meant to be a guide to arrive at balanced solutions when arranging agreements and the use of research results by commercial parties, and while taking into account the social responsibilities of the different partners.

- **Public research organisations strive to ensure that research contributes to societal and/or economic development.** Public research organisations are financed with public funding. The principle is that research must ultimately benefit society's needs, help to answer questions that are important to society and/or solve problems that are important in society and the public. Scientists must be able to point out in the social debate why particular research is done and what the expected benefit for society will be.
- **Public research organisations retain the right to continue using their own results and to let them be used for research and education.** In discussion with partners, financiers and other involved parties, the knowledge institutions will ensure that they retain the right to continue conducting their own research, verify it, teach about and publish it. This enables them to continue using knowledge developed within the institution and to ensure that other researchers can verify the outcomes. It is an important precondition for collaboration with third parties that research results can be published within a reasonable time and that essential materials and techniques for further research remain available.
- **Public research organisations make licensing agreements exclusively with parties that can reasonably be expected to continue developing the knowledge and are committed to doing so.** This principle implies concretely, for example, that no rights will be given to a party that has no intention to develop the knowledge further (but, for example, wants to buy a patent to keep its own competitive discovery exclusive).
- **Public research organisations verify that partners with whom they have arranged a licensing agreement do not have societal objectives that are in conflict with their own.** In general, it is important to know enough about the proposed collaboration partner to be able to make an estimate of their motives, objectives and willingness to be optimally transparent. The public research organisations should decide when making the agreement whether the intended partner can pass this test and must be able to support this decision with facts.



- **Public research organisations ensure that no traditional or indigenous knowledge or inventions based on it are included under intellectual property rights without appropriate agreements being made with the rights holders.** This principle concerns potential conflicts between intellectual property rights and indigenous and local knowledge. For example, genetic knowledge falls under the Nagoya Protocol and the associated legislation. It can also concern knowledge derived from long and local experience playing a role in society, behaviour, agriculture, education or sustainability, as specified by UNESCO.
- **Public research organisations, when applying these principles, take those parties that are directly concerned into account and ensure that they are adequately informed of the wishes and interests of those interested parties.** When the knowledge covered by the licensing agreement was discovered, various interested parties may have been involved, for example financiers of part projects. The public research organisation is ultimately responsible for the agreements it concludes, within the framework of any other agreements made or subsidy conditions. It is part of the public research organisation's social responsibility to take interested parties into account.
- **Protection and licences must not conflict with the legal task and societal mandate of public research organisations.** Protection can extend too far, inhibiting scientific developments because payment is demanded for the application of knowledge. The licence holder may intend to develop the knowledge in a direction that is socially undesirable or damaging, for example seeds that produce sterile offspring. Even if the partner's goals match those of the public research organisations, it can be desirable to record in the agreement documents which development or use is not desirable.
- **In certain countries, licences provide space to encourage or ensure marketing access or development, where possible. They can also offer possibilities to encourage or ensure application in certain sectors.** The public research organisations can use the licensing agreement to exercise some guidance in the way in which the licence holder markets a product or service to be developed. For example, it could be determined that products will be offered in due course at a reduced rate (based on 'cost-plus') in developing countries. Other possibilities include non-exclusive licences (partially) in certain countries, the right to grant them, agreements about a lack of protection in certain countries, agreement not to enforce such rights or grant access to local producers. When granting the licence, the access to certain sectors can



be considered. Semi-exclusive licences (exclusively for certain sectors), if sufficiently distinctive, can give partners room and security and offer a chance of wider use.

Conclusion

The intention behind adopting SRL policies is that the principles will contribute to an attitude of global access policies when arranging agreements with commercial partners. The principles presented here provide a direction, but it is not possible to determine what is desirable and undesirable for all conditions. Many considerations are involved when arranging an agreement. Ultimately, from the perspective of CropBooster-P and its daughter programme on crop-yield improvement, the primary concern is that knowledge from publicly financed research should actually contribute to society at large through improved crop yields, increased sustainability and reduced environmental impact, and guaranteed nutritional quality of food. The principles set out here can hopefully contribute to enable worldwide access to biological material when covered by patents for the purpose of vegetable breeding. The challenges mainly of legal and organisational order related to the implementation of SRL can be overcome if all the stakeholders in the future crop-yield programme work together in a trustful way with the common goal to develop a process which maximizes innovation in the FCYIP field of action.