

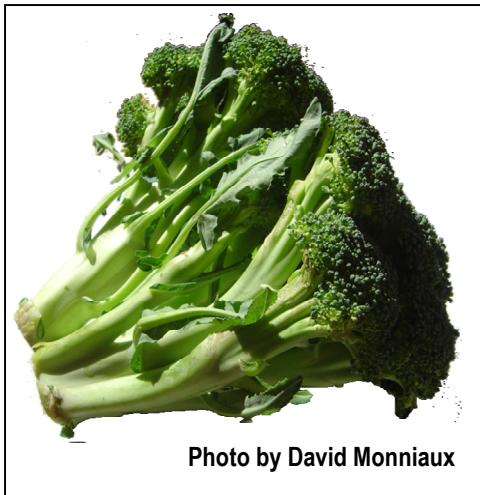


Intellectual Property in plant breeding: The battle for patents

Like in any industry, protection of Intellectual Property (IP) is essential to secure return on investment in innovative technologies in plant breeding. On the other hand, plant breeders do not want to be hampered in using the genetic material that is present in the germplasm –the collection of genetic resources- they possess. The most far-reaching form of IP is a patent. Whereas some plant breeding companies consider patents the best tools to ensure knowledge-sharing and faster innovation cycles, other plant breeders argue that patents can hinder breeding activities, have a negative impact on innovation, and accelerate the process of concentration. Notwithstanding these differences, discussions have been initiated to reach consensus.

Patents and Plant Breeders Rights

There are two types of IP rights that are relevant for the seed industry: Plant Breeders Rights (PBRs) and patent rights. While PBRs were introduced in the first half of the 20th century, patent rights became more important with the advent of modern biotechnology in the 1980s.



PBRs provide protection to the breeder of a new plant variety. A 'new' variety must meet a number of criteria to qualify for PBRs, such as distinctness, uniformity and stability. PBRs protect the variety but not the method used to develop the variety. There are also a few important exemptions to the right granted, like:

- the research exemption that allows scientist to use the protected variety for research purposes, and
- the breeder's exemption that allows another breeder to use the protected variety as basis for further breeding.

Moreover, for members of the International Union for the Protection of New Varieties of Plants (UPOV) there is an option to include the farmer's privilege permitting to save seeds.

Unlike PBRs, patent rights are granted for 'inventions' described in the claims of the patent application, provided the invention meets the criteria of novelty, non-obviousness, inventiveness and utility. A patent grants the right to the patent holder to prevent other parties to produce, use or sell the patented product(s) and process(es) without his permission. Patent rights systems do not provide for a farmer's or breeder's exemption but, depending on the territory, do provide for a (very strict) research exemption. Notably, French, Swiss and German patent legislation also do allow further breeding and product development with patented materials, although a license is needed for commercialisation. In the US, there is no exemption under patent law as in these European countries and germplasm too can be protected by patents (so-called 'utility patents').

Diverging views on patent rights

A recently published report for the Dutch Commission on Genetic Modification (COGEM) about consolidation in the global seed industry also tackles the issue of patent rights and access to germplasm. Based on interviews with ten industry executives the authors noted a divergence of opinions on the impacts of Intellectual Property laws, especially patent rights, on the structure and innovation of the seed industry. According to the industry executives, ease of access to germplasm primarily depends on the scope and nature of patent rights or PBRs and the legal costs associated with those rights.

Several interviewees argued that patents allow 'safe' disclosure of groundbreaking information about the technology, which can be used by other innovators. Patents require the disclosure of an invention in order to be granted, and are



therefore one of the best tools to ensure knowledge-sharing and faster innovation cycles. The patentability of their innovations is essential for securing an adequate return on the substantial R&D investment in the seed industry. Denying patents on plant-related innovations would have the unintended consequence of stifling innovation by causing a reversion to trade secrets as the sole remaining protection mechanism, one of the interviewees warned. One of the interviewees pointed to the value of IP as a means of creating incentives for R&D in the US soybean seed market. This market was previously largely farmer-saved seed and attracted limited private interest in breeding and technology development. Utility patents on germplasm and biotech traits enabled the profitability of the company's investments in soybean breeding.

Several other interviewees argued that patents on traits can hinder breeding activities, have a negative impact on innovation, and accelerate the process of concentration. One of these interviewees indicated that in the case of tomato breeding, patent applications for about 20 traits have been submitted; if these patents are granted, other tomato breeders will face a serious problem. A few of the interviewees speculated that this development had contributed to the decision by De Ruiter Seeds to sell its assets to Monsanto, although the company itself was also trying to acquire strong patent positions, in order to stay in business. According to one of the interviewees, the possibility to protect germplasm with utility patents in the US has narrowed access to germplasm for universities, public institutions and smaller breeding companies in the US. It also has resulted in a faster consolidation in germplasm, especially among big seed companies, because these companies prefer utility patents over Plant Variety Protection, a form of PBRs.

A patent machine for carpet bombing?

One of the interviewees in the COGEM study expected that within less than 5 years the complete genome of about 20 crop species will be fully covered by patents because of the patentability of 'native traits'; traits that exist in nature. There is already a lot of activity in high-throughput sequencing, a fast and cheap technology that provides data about the genotype. "Add to this", the interviewee said, "high-throughput technology for determining the phenotype, the bio-informatics computing power to put all data together, and on top of that, a bunch of lawyers for meeting patenting requirements, what you then in the end get is a 'patent machine for carpet bombing'. This will result in a completely unworkable situation because it will lock access to germplasm and genetic diversity. It will also endanger diversification of germplasm, another interviewee suggested, while there is a lot of breeding potential to unlock germplasm, and plant breeders need broad diversity for improving their gene pools."

Including breeders' exemption into patent law

In May 2009, Plantum NL, the Dutch seed industry association, has proposed to amend patent law. By inclusion of a breeders' exemption into patent law, genes and genetic components in plants could be made freely available for the development of new varieties. Patented biological material (germplasm) should be freely available for breeding new varieties and the use of these varieties should be consistent with the breeders' exemption of the UPOV Treaty. Availability, use and exploitation should not be hampered by patent law. New methods and techniques should continue to come under patent law, though.

One of the interviewees in the COGEM study explicitly argued that the position by the Dutch seed industry association would be detrimental to investment; see position text box below. According to this interviewee, the argument that patents may hinder innovation is not correct. In his view patents do promote innovation but at the cost that patents may (temporarily) restrict the use of innovations. Several other interviewees argued that patents on traits can hinder breeding activities, have a negative impact on innovation, and accelerate the process of concentration."

Exemption of 'essentially biological processes'

The EU-SOL programme was focused on consumer traits like improved taste and health. Hence, the ruling of European Patent Office's Enlarged Board of Appeal (EBoA) on the validity of two recent patents in this field in December 2010: a patent granted to UK company Plant Bioscience in 2002 for an anti-carcinogenic broccoli strain and one awarded to Israel's Ministry of Agriculture in 2003 for a flavour-enhanced tomato. These patents include a number of claims on both the methods and the final product. Challenges to these patents from corporations such as Unilever and groups such as the No Patents on Seeds movement insisted that the underlying features of the patents were essentially biological rather than technical and, as a result, fell within the scope of Article 53(b)'s which exempts



“ for the production of plants or animals from patentability. Because of similarities between the patents and their respective challenges, the EBoA tied them together as one case for review.

In its ruling the EBoA focused on the patent claims that concern the methods. According to the EBoA, technical devices or means, such as genetic markers, may themselves be patentable inventions, but their use does not make an essentially biological process patentable. Processes for producing plants by inserting or modifying a trait in the genome by using genetic engineering do not rely on sexual crossing of whole genomes and may therefore be patentable. However, in such a case sexual crossing and selection steps should not be in the claims, since adding further technical processing steps before or after the steps of sexual crossing and selection does not render such processes patentable either. It is important to note that EBoA's ruling does not concern the claims concerning the final product. Therefore it remains possible to claim, for instance, a flavour enhanced tomato characterised by.....

A number of interviewees in the COGEM study distinguished between patents on what they called 'native' traits, and patents on GM traits. Since native traits are already present in the crops and their wild relatives, patents on native traits could affect the access to a breeder's germplasm. For GM traits, several interviewees commented, it is different because of the level of investment and regulatory compliance costs.

IP in EU-SOL

When a workpackage or task has been completed or when a concrete result(s) has been obtained, the partner(s) who carried out the research investigate whether or not the obtained result(s) can be protected by filing a patent or whether additional research is necessary. The possibilities for protection of Intellectual Property Rights is always assessed. The outcome of these evaluations, including a plan regarding filing and exploiting a patent, will be sent, under a confidentiality agreement, to the Industry Evaluation Panel (IEP), consisting of representatives from EU-SOL industrial partners, the workpackage leaders involved in dissemination of EU-SOL knowledge and transfer of technology to industry and the EU-SOL coordinator. The inventing partner(s) will own the intellectual property rights and is responsible for providing adequate and effective protection for the knowledge. The IEP facilitates these activities and EU-SOL allocated budget to cover the expenses for the initial registration of the patent applications. So far, two patents have come through the IEP:

- A flavor patent application on alpha-copaene (Ducruex, 2008);
- A patent application on Induced Heterosis Related Mutations (<http://www.wipo.int/pctdb/en/wo.jsp?WO=2010041190>) for yield in determinate tomatoes, which has the potential to transform the market by inducing ~50% increase in yield the raw experimental data and analysis tools via Phenom Network (<http://phnserver.phenome-networks.com/>). See also EU-SOL Newsletter 06: "Boosting tomato yield and sweetness".

To be continued.....

The European Seed Association (ESA) and the International Seed Federation (ISF) always had the position that commercially available material containing patented elements should remain freely available for further breeding. It is therefore not surprising that several of the interviewees in the COGEM study believe that a consensus seems to be emerging within the about the exemption under patent law, similar to the exemption in current French, German and Swiss patent laws, which allows pre-commercial product development. A number of interviewees argued that such an exemption under patent law will allow more seed companies breeding their products more broadly, as they can test and work with the technology prior to its commercialisation. On the other hand, it can be argued that such an exemption is unlikely to have an effect at all as breeders will not start using patented material in a breeding program without the certainty that it will be allowed to commercialize possible new varieties resulting from such a program. It will therefore need a license before starting the use of the material in the breeding program.

References:

European Patent Office: No European patents for essentially biological breeding processes, 9 December 2010, <http://www.epo.org/topics/news/2010/20101209a.html>

Schenkelaars, Piet, Huib de Vriend and Micholas Kalaitzandonakis (2011). Drivers of Consolidation in the Seed Industry and its Consequences for Innovation. COGEM onderzoeksrapport CGM 2011-01, 14 January 2011,



<http://www.cogem.net/ContentFiles/CGM%202011-01%20drivers%20of%20consolidation%20in%20the%20seed%20industry%20and%20its%20consequences%20for%20innovation.pdf>

European Patent Specification EP 1 069 819 B1, Method for Selective Increase of the Anticarcinogenic Glucosinolates in Brassica Species, Patent application by Plant Biosciences Ltd., 24.01.2001. <http://www.no-patents-on-seeds.org/sites/default/files/patente/anmeldung/ep1069819b1.pdf>

European Patent Specification EP 1 211 926 B1, Method for Breeding Tomatoes Having Reduced Water Content and Product of the Method, Patent application by the State of Israel Ministry of Agriculture, 12.06.2002. <http://www.no-patents-on-seeds.org/sites/default/files/patente/anmeldung/ep1211926b1.pdf>

Louwaars, Niels *et al.* (2010). Breeding business: The future of plant breeding in the light of developments in patent rights and plant breeder's rights. Centre for Genetic Resources, The Netherlands, CGN Report 2009-14 (EN), December 2009. <http://documents.plant.wur.nl/cqn/literature/reports/BreedingBusiness.pdf>

Ducreux, Laurence J.M. *et al.* (2008). Expression profiling of potato germplasm differentiated in quality traits leads to the identification of candidate flavour and texture genes, *J. Exp. Bot.* 2008;59(15):4219-31. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2639024/pdf/ern264.pdf>

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