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REVIEW

Seed science in the 21st century: rights that scientists have to deal with

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Abstract

Seed researchers, like anybody else working with materials containing genes, have to deal with a variety of rules. Their 'freedom to operate' does not only depend on intellectual property rights but also on various rights arising from biodiversity policies and possibly traditional knowledge. The most relevant are, however, patents on both materials and biotechnologies. It is in this field that recent developments indicate that the pendulum of ever-increasing levels of rights has started to swing back a little. This is due to recent court cases both in the USA and Europe, and emerging political debates in various countries. After describing the general policy arena involving national sovereign rights, private rights and 'group-rights' we focus on recent trends in the patent system. Seed scientists hardly even had to deal with such rights in the past, but in the 21st century they need to be aware of their implications.

Keywords: biodiversity rights, genetic resources, intellectual property rights, policies, seeds

Introduction

Seed scientists work with living materials that may fall under a variety of legal regimes at the same time. Even though the Food and Agriculture Organisation (FAO) International Undertaking (FAO, 1985) formally designated genetic resources for food and agriculture as a 'heritage of mankind' to be freely used by anybody, and intellectual property rights (IPRs) did not affect scientific work on higher plants at that time, a number of international agreements and changes in national application of existing laws have changed the legal environment in which seed scientists operate (Louwaars, 2006). Seed researchers may not always be aware of these regulatory issues. Therefore, this paper provides an overview of developments at the international level, with specific emphasis on the trends in patenting plants and their components.

Biodiversity policies

Plant genetic resources became part of a binding international agreement in 1992. The Convention on Biological Diversity (CBD) brought all genetic resources, including those used in agriculture, under the sovereignty of nations (www.biodiv.org). This means that countries can make access to such materials subject to mutually agreed terms and prior informed consent. In practice this means that most genetic resources, collected after the coming into force of the CBD in 1993 are bound to a material transfer agreement that may specify limitations to their use in research and/or product development. Countries may impose widely different conditions of access to their genetic resources. This could restrict availability of genetic resources for research, and put the commercialization of products arising from such research subject to conditions, notably the equitable sharing of

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benefits with the provider, i.e. the country and its local and indigenous communities. This 'Access and Benefit Sharing' (ABS) was a key element in the latest Conference of Parties of the CBD (Convention on Biological Diversity, 2010). The Nagoya Protocol, which was concluded in 2010, provides the basis of internationally applicable rules for ABS that could facilitate both access and benefit sharing.

Particularly to serve the needs of the agricultural sector, the FAO through its Commission on Genetic Resources for Food and Agriculture identified limitations in the implementation of the CBD with respect to agricultural use of genetic resources. The key element appeared that the large number of exchanges world-wide of these specific genetic resources created problems with the mechanism of bilateral negotiation for access. Furthermore, the position of the international genebanks had to be clarified, as were the other supporting components that had already been developed, such as the Global Plan of Action (1995) (www.globalplanofaction.org). The 'International Treaty on Plant Genetic Resources for Food and Agriculture' came into force in 2004. An important component is the multilateral system which facilitates access to genetic resources of major food and fodder crops and arranges for multilateral benefit sharing. These materials are shared using a standard material transfer agreement, which specifies, among other things, that users may not take out patents on the materials 'in the form received'. Also, the Treaty specified some content on the concept of Farmers' Rights, which member countries have to implement at the national level (FAO, 2001).

A third process which may become very relevant concerns the negotiations in the Intergovernmental Commission on Genetic Resources, Traditional Knowledge and Folklore, (IGC) which focuses on the (traditional) knowledge component of genetic resources (www.wipo.int/tk/en/igc). This committee has not created an international legal instrument yet, but some countries have already introduced national legislation with regard to traditional knowledge which may affect access to plant materials.

Relevance for seed scientists

For seed scientists it is important to know that these agreements and the national laws derived from them may all create legal restrictions on the use of plant materials, and that seeds that are included in research may have come with contracts attached to them. Seed scientists need to verify the origin of the seeds that they use. Particularly, those using seeds with particular natural traits, or seeds of under-researched plant species, may need to know whether there are any strings attached to the use of the seed. In cases of seeds obtained from the wild, or from a particular community, it is important to obtain approval based on prior informed consent from the national competent authorities and – depending on national law – from the communities/land owner/local authorities in the area from which the seed, and possibly associated traditional knowledge, originates. This is particularly important for seed ecologists studying the dispersal of the natural flora and coping mechanisms based on seed physiology or morphology of species.

If seed is obtained from a person who got them from such primary sources it is also important to find out whether approval has been obtained and which conditions have been set, i.e. whether agreements have been concluded that affect the use of such seed. Failure to do so may have at least diplomatic and sometimes legal repercussions. If seed has been obtained legally, it is essential that the conditions of the material transfer agreement are respected. These may range from an obligation to recognize the origin in publications to requirements for scientific co-operation or technology transfer, or other sharing of (non-) monetary benefits.

Intellectual property rights

Until the mid-1980 s, plants had not been subjected to patent protection. The agricultural community had developed its own system for the protection of plant breeding. Plant breeder's rights – later dubbed Plant Variety Protection – do not restrict the use of seed in research. The rise of biotechnology, however, introduced patent rights into plant research, first through court decisions in the United States of America (Box 1) and much later through the adoption of the Biotechnology Directive of the European Commission (Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, PB.L., no. 213, 30 July 1998, p. 13), making both biotechnological processes and products subject to patent protection.

At the global level, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organisation has had a tremendous effect on the protection levels of intellectual property rights at the global level. For example, India had to provide patents on products, whereas before the TRIPS-based changes of the national patent law only processes could be protected. However, TRIPS includes an important exemption relevant to plant scientists in its Article 27(3)b. Countries may exclude plants and animals from patentability (but then have to provide for a protection of plant varieties), which is interpreted, for example in several African

Box 1. Landmark decisions on patents in the USA.

- *Diamond* v. *Chakrabarty* 447 US 303, 206 USPQ 193 (1980), which involved the first patent on a man-made micro-organism.
- Plants were considered patentable following the ruling in ex-parte Hibberd, *227* U.S.P.Q. 443 (Bd. Pat. App. 1985).
- In *J.E.M. AG Supply Inc*. v. *Pioneer HiBred International, Inc*. 534 US 124, the US Supreme Court held that utility patents may be issued for plant varieties and plant seeds, and that rights under either the Plant Patent Act of 1930 or the Plant Variety Protection Act of 1970 would not reduce the patentability.

Source: Louwaars *et al.* (2009)

countries, as an exclusion of parts of plants such as traits and genes as well. Also, Brazil, an important agricultural country, has resisted the patenting of genes (Octaviani, 2010).

However, in major jurisdictions, a wide range of technologies and biotechnology products can be patented. Initially, patents were restricted to sequencing and the resulting expressed sequence tags (ESTs), and, on the other hand, transgenics, with protection of transformation and regeneration protocols, promoters and functional genes involved in genetically modified crops. However, the number of patents has increased significantly over the past decade with the creation of new applications of molecular biology in the plant sciences, such as marker systems, molecular mutagenesis, reverse breeding and cis-genesis. These technologies also yield the identification of many (single and multiple) genes and their functions that – even though they concern naturally occurring genes – may be patented. In Europe this followed a decision on appeal number G1/98 by the Enlarged Board of Appeal on patent no. EP 0448511 B1of Novartis, which specified that despite the fact that plant varieties cannot be patent protected, patents can be obtained on traits that are not confined to one variety.

The biotechnology sector provides excellent opportunities for strategic use of the patent system (Louwaars *et al.*, 2009). Wide claims are particularly common in the early days of a technology. Therefore a claim on all genetically transformed cotton based on the first transformation technology was initially honoured (and later withdrawn). Furthermore, reach-through claims can be commercially very interesting, i.e. a technological invention, claiming all materials created with that technology plus all the offspring created therefrom – and potentially the products harvested and produced from such plants. Finally, blocking patents can be useful to prevent competitors enter a particular research domain. Such uses of the patent system carry the risk of developing patent thickets (Bobrow and Thomas, 2000; Reitzig, 2004), leading to restrictions for further research and thus contributing to a tragedy of the anticommons (Heller and Eisenberg, 1998). Even though patent thickets may not be impenetrable for those who have the legal and technical capacity to study patent landscapes in detail, for smaller companies and universities the existence of a multitude of patents in any particular research area is likely to deter them from pursuing their research (Louwaars *et al.*, 2009).

Recent trend: increasing debate on the roles of patents

The patenting of plants is the lifeline of important subsectors within the global seed world, notably the maize seed business. Other breeders and seed companies have to determine whether they could play the game or whether they should oppose it. Plantum.NL, the Dutch seed association, has taken an explicit position in this debate by stating that the patent system is stifling innovation and should be changed by exhausting the patent rights on plant biotechnological inventions at the level of the use of materials in practical variety development (Plantum, 2009). They call for a 'breeder's exemption' as in plant breeder's rights, including materials that fall within the claim of a patent. This would make all modern varieties available for further breeding by all breeders, which has been the practice in the plant breeding sector under the concept that plant breeding is a cumulative enterprise – that all breeders stand on the shoulders of their predecessors, including the generations of farmers who developed the crops from their weedy ancestors. Unlike common-law countries, such a change in Europe calls for an amendment of patent law. The position was based on a majority vote of the membership of the Dutch seed association with – initially – only the few large multinational company members of Plantum.NL opposing. In response to this position the Dutch ministries of agriculture and the economy called for a study on 'the future of plant breeding in the light of developments in patent rights and plant breeder's rights' (Louwaars *et al.*, 2009).

Based on literature research and interviews, the study identified that the concentration in the global seed sector (Le Buanec, 2007) is triggered by three major causes: cost of new technologies, general globalization of trade and patents. It concluded that if

- breeding is to continue to be a main tool towards food security and sustainable agriculture;
- access to genetic resources is considered important;
- innovation strength of the sector is to be preserved/increased;
- diversity of companies is key for healthy competition;
- the Dutch breeding sector is to safeguard its position;
- a decent profit margin is to be made possible; and
- IPRs are considered to be one of the keys;

then the following three actions should be considered to improve the patent system:

(1) The industry itself could – through a code of conduct – reduce strategic uses of the patent system that are considered most detrimental to downstream innovation at the level of plant breeding.

(2) The patent offices should play an important role in increasing patent quality, thus reducing the number of plant science patents, improving the clarity of the boundaries of claims and of the enabling publication of the invention.

(3) Change of patent law to include a breeder's exemption. This could be done at three levels:

  (i) allow the use of plant materials falling within a patent claim for further breeding, but when a patented component (trait or other construct) is present – and functional – in the new variety, then consent needs to be sought from the patent holder;
  (ii) a full breeder's exemption, meaning that any material can be used for further breeding and the new variety may be freely marketed by the breeder; and
  (iii) exempt plants and their components from patent protection.

Finally, the study stressed taking the following policy fields into account:

- competition law, which deals with the other side of the monopolies created by IPRs;
- development policy, basically stressing that if the Netherlands wants to balance the rights of the inventor with those of society, developing countries should not be forced in bilateral trade negotiations to strengthen their IPRs beyond their immediate needs;
- public research policies, making sure that such research contributes to public values (De Jonge and Louwaars, 2009) and does not unnecessarily contribute to patent thickets, and that research areas that the private sector may leave, because of lack of incentives, will be covered.

The debate in parliament led to a request to the seed association Plantum.NL to develop two working groups, consisting of different types of companies, to identify opportunities to develop a solution to strategic patenting. Ideas were developed to create patent pools and to exempt natural genes from patentability. The groups have not yet concluded their deliberations.

The government furthermore confirmed that patents and plant breeder's rights seem out of balance, that access to genetic resources needs to be supported, and that the ministers will raise the issue in their respective tasks in the European Commission. Further, that support to the 'raising the bar' process at the European Patent Office (EPO) would need to be given. By the time of the report the EPO had already presented an initiative to do this under the title 'raising the bar'. However, patent offices need to take into account that raising the bar too much could invite large numbers of court cases. In addition, the International Seed Federation started a programme to educate patent examiners at the United States Patent and Trademark Office (USPTO) and EPO in methods of plant breeding, with the aim to better identify innovativeness (non-obviousness) of claims involving selection methods.

Finally, the ministers promised further research to identify the legal consequences of the options to change patent law. That analysis concluded that the first option (restricted breeder's exemption) is possible since other European countries had already introduced such clauses in their national patent laws; that the full breeder's exemption, which makes some types of patents virtually worthless, may create a conflict with Article 30 of TRIPS which states: '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.' Finally, exempting plants from patent protection is explicitly compatible with TRIPS but conflicts with the Biotechnology Directive of the European Union. Furthermore, such a solution to the problem in the plant breeding sector would also have severe repercussions to other technology sectors that use plants, such as pharmaceutical and industrial biotechnology.

Has the pendulum started to swing back?

Since the decision in the Chakrabarty case in the USA in 1980 (see Box 1), more and more outcomes of plant biotechnological research have been protected by patents, the vast majority of which are held by very few companies (Louwaars *et al.*, 2009). The pendulum has been swinging in that upward direction until recently.

The debate in society is much broader than the discussion triggered by Plantum.NL and is contributing to a number of decisions that has an increasing impact on the patenting of life. These court decisions, in both the USA and Europe, are attacking patent claims from all possible sides. First the utility (industrial application) requirement was put to the test when patents on ESTs were abolished following *in re* Fisher 421 F.3d 1365 (Federal Circuit, 2005). In April, 2009 a potentially far-reaching conclusion was reached by the United State Court of Appeals for the Federal Circuit *in re* Marek Z. Kubin and Raymond G. Goodwin (http://www.cafc.uscourts.gov/opinions/08-1184.pdf) which considered a patent for a gene that codes for an already known protein not unobvious (not inventive). This could impact a particular class of gene patents. Finally, the District Court of New York arrived at a very far-reaching verdict in the opposition by the Association for Molecular Pathology against a patent granted by the United States Patent and Trademark Office (Case 1:09 cv-04515-RWS; http://www.aclu.org/files/assets/2010-3-29-AMPvUSPTO-Opinion.pdf) involving a human gene coding for susceptibility to breast cancer. If this reasoning holds in the higher courts, this would likely nullify all claims on naturally occurring genes.

In Europe, two recent cases (December 2010) contributed further to the expectation that the pendulum may be swinging back. In a case on Argentine soybean meal originating from herbicide-tolerant (Roundup-Ready) soybean on which Monsanto claimed rights in Europe, the patent owner lost because, even though the patented gene may be present in the ground soy, the gene was considered not functional in that state and thus the patent rights exhausted. The full consequences of this decision by the Grand Chamber of the European Court of Justice (case C/428-08; C:2010:234:0007:0008:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri = OJ:C:2010:234:0007:0008:EN:PDF) – for example on health claims based on genes – are not clear yet, but it showed a critical attitude to the rights of patent holders. The swing was further confirmed by a decision of the Enlarged Board of Appeal of the European Patent Office in December 2010 (G 2/07 and G 1/08 for broccoli and tomato, respectively; http://www.epo.org/news-issues/news/2010/20101209a.html), turning down patent claims on natural genes and breeding methods to transfer such traits in plants. It is likely that the courts on both sides of the Atlantic are sensitive to the public debate regarding the patenting of life forms, which shows – similar to the upswing of the pendulum in the 1980 s – that the courts are indeed part of society.

Relevance of IPRs for seed technologists

IPRs may create opportunities for seed technologists to develop spin-off companies from university research, or commercial markets for inventions such as seed treatment methods. Patents, however, may also create restrictions to the use of both materials and technologies in research. It is important to know the scope of the research exemption in your country (Ludwig and Chumney, 2003; Waltz, 2009), and identify which types of risks the use of patented technologies carry. These may vary in the research phase and in the creation of commercial products out of such research. If research is aimed at producing practical uses, it may be useful to do a Freedom-to-Operate analysis before using seeds that may carry patented traits or that may be included in other patent claims. This is important because, if something useful comes out of the research, the patent holder may be allowed to claim exclusive rights on such uses.

Conclusion

Even though rights on the materials and the technologies that seed scientists use may not be at the forefront of the scientist's mind, they may require some serious considerations in 'seed science in the 21st century'. There are some trends for both biodiversity rights and intellectual property rights to become a little bit more manageable, but both types of rights can significantly affect the freedom to operate in both research and product development based on seed science and technology.

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