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THE MANAGEMENT OF INTELLECTUAL PROPERTY RIGHTS IN PLANT BIOTECHNOLOGY

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Bernard Le Buanec – ISF

The subject proposed by the organizers, "The management of intellectual property rights in plant biotechnology," is extremely broad. It is certainly difficult to give it exhaustive and detailed coverage in the course of a 15-minute presentation. In particular, it may be asked where the management of intellectual property rights begins and where it ends. Should the policy of publishing research results and the correct application of procedures for safeguarding the secrecy of know-how be included?

In this presentation, I will restrict myself to:

- an introduction to the different forms of protection which affect plant biotechnology;
- the management of a portfolio of rights;
- the search for licenses and the "freedom of operation."

1. The different forms of protection

Biotechnology inventions in the field of plants and agriculture are not commercial goods marketed as such for a final user. They are marketed through plant varieties which incorporate them or products obtained, be it directly or indirectly, from the varieties in question. Their protection, either direct or indirect, therefore depends on different laws according to the country in question.

- for biotechnology inventions themselves, essentially patents, but also secret know-how and material transfer agreements;
- for plant varieties containing these biotechnology inventions, plant variety protection certificates (PVPs), in certain countries patents and other legal mechanisms.

Consequently, the environment of intellectual property rights in plant biotechnology has now become very complex.

2. The management of intellectual property rights

2.1 Management of a portfolio of technologies

As a rights' holder, attention should be paid to:

- protection against the fraudulent use of a patented invention by a competitor in order to develop new products;
- protection against fraudulent use by a final user;
- the management of the patent portfolio by licenses and material transfer agreements.

2.1.1 Protection against the fraudulent use of the patented invention by a competitor in order to develop new products

This is a relatively conventional situation, which is not specific to plant biotechnology. Commercial and bibliographical supervision is required in order to verify the appearance of new products and any possible application for protection in relation thereto. In cases where counterfeiting is suspected, it is necessary to contact the counterfeiting party in order to find an amicable solution, or take the matter to arbitration or to the courts.

The introduction of the concept of an essentially derived variety for the varieties protected by a plant variety protection certificate extends the obligation for technological supervision and actualizes the fraudulent or non-fraudulent nature of the use of the patented invention in the research phase.

2.1.2 Protection against fraudulent use by a final user, in general a farmer

This is a much more difficult situation since the essential property of a biotechnology invention, inserted in a plant variety, is to be self-reproducing. This is quite similar to electronic piracy but the counterfeit product can be made even more general, since it requires no investment other than the original seed. There are therefore millions of potential counterfeiters. The only solution is to inform the user appropriately and to undertake surveys. In certain countries, seed companies have come together to defend their rights and have formed contracts with private and professional surveyors. However, given the large number of possible cases of counterfeiting and the low value of each case, the cost of supervision and of legal action is often not justified, other than to establish a precedent.

The situation is complicated still further as a result of the lawful or unlawful use of farm seeds. This is an extremely sensitive subject at the international level.

In the United States, where the protection given by a PVP certificate is non-existent in this area, farmers usually produce their seeds themselves for autogamous plants and would like to be able to continue to do so, irrespective of the varieties in question. Furthermore, two members of the House of Representatives introduced a Bill on July 8, 2003, designed to authorize the farm seeds of genetically modified varieties.

In Europe, the Directive on the protection of biotechnological inventions provides that the authorization to produce farm seeds for the varieties protected by a PVP, in return for financial compensation for the breeder, should be extended to transgenic varieties.

In conclusion, this aspect of the management of intellectual property rights is complex, costly and politically sensitive.

2.1.3 The management of the patent portfolio by means of licenses and material transfer agreements

The developers of biotechnology inventions, known as biotechnology suppliers, use two principal means to enhance their research work:

- either they commercialize plant varieties including their inventions themselves;

- or they authorize third parties, on the basis of licenses, to use those inventions in their own varieties.

These means are not mutually exclusive and biotechnology suppliers implement a “mix” with more of one or the other, according to the companies.

The licenses may be subject to a fee or are free of charge according to the licensee. Free licenses are more and more the case for public research in developing countries. Numerous examples are known, one of the most widely publicized being the case of Golden Rice.

The recent creation of the “African Agricultural Technology Foundation” is a second example of free licenses used by four companies: Monsanto, DuPont, Syngenta and Dow AgroScience. The aim of this Foundation is to enhance, by means of genetic engineering, the crops of importance to small-scale African farmers.

Another means, used more and more widely in both the public and private sectors, is the material transfer agreement. This is a binding private contract between the technology supplier, irrespective of whether the technology is patented, and the person who receives the technology. The contract allows the receiving party to undertake research work but it often contains very restrictive clauses for that party such as:

- the obligation to provide information on the work undertaken, leading to risks of disclosure of the research strategy;

- exclusivity;

- shared ownership of the results;

- responsibility for any damage or risk stemming from the use of the transferred material.

Furthermore, the commercialization of a product subsequently requires a commercial license.

The research license is a mechanism similar to the material transfer agreement for patented inventions.

2.2 License search and "freedom of operation"

Intellectual property rights are crucial for the development of new plant varieties. During the past 30 years, the growing interest of the private sector in the seed industry and, more particularly, during the past 15 years in plant biotechnologies means that most of the technologies and germplasm are subject to commercial control. Public research also has, on more and more occasions, protected its results. The scope of "public good" has therefore been considerably reduced and freedom of operation has become a major concern for the parties involved.

This requires significant means and different approaches are used:

- large companies have their internal scientific and technology monitoring units which allow them to monitor patents at the international level;

- small and medium-sized enterprises can group together to establish a collective monitoring unit, as is the case in France with VIGIBIO;

- several semi-public or public initiatives have also emerged:

  - in July 2001, CAMBIA (acronym for "Center for the Application of Molecular Biology to International Agriculture"), an independent non-profit making organization based in Canberra, made public a database on patents in the field of biotechnologies, known as the CAMBIA Intellectual Property Resource or CIPR;

  - more recently, in 2003, a number of public research unit heads in the United States have also launched an initiative of the same type, known as PIPRA, the Public Sector Intellectual Property Resource for Agriculture.

  All these initiatives have the same aim: to provide awareness of the prior art and its legal position, avoid using technologies which do not appear to be freely accessible, and to negotiate licenses or cross-licenses.

  The members of the ISF are not in favor of compulsory licenses. It should, however, be known that the Agreement on Trade-Related Aspects of Intellectual Property Rights, (TRIPS Agreement) allows the principle of such licenses (Article 31.1) "to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), [if] the following additional conditions shall apply:

  - the invention claimed in the second patent shall involve an important technical advance of considerable economic significance, in relation to the invention claimed in the first patent;

  - the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent […]."

The spirit of this provision of the TRIPS Agreement is reiterated in full in Article 12 of the European Directive 98/44/EC on the legal protection of biotechnological inventions for cross-licenses between a plant variety protection certificate and a patent.

This point leads me to deal with a particular problem for which no clear solution yet exists in certain countries and which is a subject of significant debate in the breeders' community. I am referring to the use of varieties protected by a PVP and containing patented elements. Until the recent past, the freedom of operation for research was complete for the varieties protected by PVPs, where they had been obtained by lawful means. This possibility is known as the "breeders' exception." Varieties protected by PVPs and containing biological material protected by a patent are now on the market. What is the situation with the "breeders' exception" in this case, since in most countries the protection of biological material granted by a patent is extended to all biological material derived from the protected biological material? Is there still freedom to operate? It seems that in certain countries such as the United States, the response is clear but negative. In Europe, there is great uncertainty and opinions differ. At the 1998 ISF Congress, the rapporteur for the European Directive, Mr. Willy Rothley, said that the Directive and its preamble did not provide the necessary response and that, in order to clarify the matter, decisions forming case law would be necessary.

However, the debate is not only one of legal interpretation. It is also internal to the seed industry in relation to the desirable objectives. At its Congress in Bangalore last June, ISF adopted the following position by a very large majority (86 per cent): the ISF is strongly attached to the breeders' exception stipulated in the UPOV Convention and is concerned with the fact that the extension of the protection of a genetic sequence to the appropriate plant variety may bring an end to this exemption.

Consequently, the ISF considers that a commercially available variety, protected only by a PVP and containing patented elements, should remain freely available for new selection work. If a new plant variety resulting from this new selection work, which is not an essentially derived variety (EDV), is outside the scope of the patent claims, it can be freely exploited by its developer. By contrast, if the newly developed variety is an EDV or it is included within the scope of the patent claims, the consent of the owner of the initial variety or the patent must be obtained.

The debate continues within the ISF and to shed further light on the matter, an international seminar on access to genetic resources will be organized in May 2004 in Berlin.

3. Conclusions

The issue of intellectual property rights in plant biotechnology has, in the past few years, become extremely complex, irrespective of whether it is a matter of a rights' holder who wishes to defend and enhance those rights, or whether it is hoped to define the scope of freedom of operation by moving beyond the limits of the existing rights or negotiating research agreements.

The complexity is increased as a result of the method of enhancing plant biotechnology inventions protected by patents, using plant varieties which in most cases are protected by PVPs. Two rights therefore exist, with a coexistence not always easy to define, especially since these issues, which are technically complex, are politically and socially sensitive.

Finally, it should be noted that, in terms of time for developing doctrines, these problems are relatively new. A further few years are required for users to reach agreement on the desirable objectives and for case law to clarify the debate.

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