UDK 347.77:[631:575

INTELECTUAL PROPERTY RIGHTS PROTECTION IN AGRICULTURE:GENE AND ORGANISM PATENTING

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Abstract

Intellectual property rights and patents are another subject of dialogue with ethical dimensions. Society encourages investment in research and development by allowing inventors to protect their discoveries with patents. The reason controversy surrounds the patenting of genes and of seeds is that our relationship to food and farming is very different from our relationship than to industrial products. We balk at the notion that an entire gene family or a plant species constitute a patentable invention. Does the practice of patenting genes encourage or inhibit research? The preoccupation of many universities with patent protection and licensing agreements become a distraction to researchers and an impediment to the free flow of ideas and materials. Licensing agreements become a distraction to researchers and an impediment to the free flow of ideas and materials? The issue of equity also arises with respect to intellectual property rights and the ownership of genes and genomes. Companies or university researchers use germplasm from developing countries to isolate important genes. They should not be free to patent those genes without rewarding these people who propagated the germplasm for centuries? Genes and genomes belong to all humankind and are too important to be restricted from free access and use by all. The best example of this was the race to publish public databases for humans and Arabidopsis so that companies could not patent the basics of plant and human genomes. Cases in plant breeding rights protection will be discussed.

Key words: agriculture, intellectual property, patenting, gene,protection

Introduction

Historically, the patent system came to birth to meet industrial needs. Industry was perceived as activities carried on inside factories... Manufacture was the key word. Agriculture was felt to be outside the realm of patent law. Living things were also assumed to be excluded as being products of nature rather than products of manufacture... This restricted view no longer persists in most industrialised countries. Thus the European Patent Convention of 1973 declares agriculture to be a kind of industry. (Crespi,1989)

Over the past century, agricultural research has a global record of extraordinary achievement. food supply has outstripped population growth for many decades. The result is that the world population has, on average, larger body size, greater work capacity (Fogel, 2004), and longer life span (Fogel, 2004).

Private producers have often specialised in the provision of clean pure seed for planting many self-propagating crops. But these producers have not devoted great resources to the development of new, higher-yielding varieties. The large yield-increasing innovations in the major, non-hybrid food crops were achieved by public sector and non-profit institutions including universities, government-sponsored research agencies and experiment stations.

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In the past quarter-century, a revolution in intellectual property protection has radically altered the set of opportunities for financing and encouraging innovations in crop breeding and related areas.

Plant Variety Protection has been used extensively in the seed industry to control reproduction of commercial varieties (as opposed to breeding) in agriculture and horticulture, and to protect valuable newly-discovered mutations in horticulture. It has also been used to protect the parents of hybrids from unauthorised use by competitors (generally other breeders, rather than farmers, in this case) to produce commercial hybrid seeds.

In 1982, enforcement of patent rights was effectively strengthened by making the Court of Appeals of the Federal Circuit responsible for appeals of patent decisions (Jaffe, 2000). These legal changes transformed the intellectual property protection environment of agricultural biotechnology in the USA. But they also constituted the opening moves in a sequence of legal changes in Europe, Japan, and other developed countries that followed, to varying degrees, the USA lead (Jaffe,2000)

Concentration in the global agricultural biotechnology industry is inevitable, given the high fixed cost and low variable costs associated with the technology. The top firms spend impressive sums on research and development, led by Monsanto which regularly has spent more than one half a billion dollars per year; several more spend around half this sum on agricultural biotechnology research and development. Given these commitments, it is clear that the industry must have the market power necessary to charge well above short run marginal cost if it is to survive.

Crops such as commercial hybrid maize cannot be reused if hybrid yield and vigour are to be maintained. This characteristic of some hybrids confers a natural form of protection by which seed companies can more readily capture a return on their investment through repeat seed sales. By contrast, other types of seed variety can be replanted each year without deterioration in yield, so that farmers may replant their own seed without repurchasing.In addition, patents are widely used to protect the technologies which are employed in research on plant genomics.

Protection would thus be on two levels: free open access to the genetic diversity of plant varieties, and limited access to the specific characteristics that compose a plant variety. This essential derivation on specific characteristics of plant varieties protected by Plant Breeders' Right is necessary, because there is no longer any free open access without contracts to genetic diversity, except in the case of plant varieties protected by Plant Breeders' Right. We are moving toward a world in which access is guaranteed but in a contractual way, to limit the risks of privative appropriation. As recalled by Henry *et al.* (2007): "The contract avoids the abusive and [confiscatory] appropriation by a third person." (Henry et al.,2007) Access to genetic diversity that is as rapidly available as possible for the competitors is all the more necessary if a company is working to introduce several characters into the same variety; the time required to create new varieties is again long, over ten years.

Farmers have traditionally replanted, exchanged or sold seed from the previous years' crop which means that breeders have difficulty in recouping the investments made in improved varieties through repeat sales. Patents or PBRs normally impose restrictions on farmers' ability to sell grown seed (and in some cases to reuse it) and thus enhance the market for the breeder's seed. Even in the developed countries, reuse of seeds remains quite common although for many crops annual purchase is now the rule. In developing countries the majority of farmers reuse, exchange or sell informally to neighbours, and annual purchase of new seed is relatively rare in most countries.

The intellectual property in plants can be appropriated by technological means. For instance, crops such as commercial hybrid[6] maize cannot be reused if hybrid yield and vigour are to be maintained. This characteristic of some hybrids confers a natural form of protection by which seed companies can more readily capture a return on their investment through repeat seed sales. By contrast, other types of seed variety can be replanted each year without deterioration in yield, so that farmers may replant their own seed without repurchasing.

Technical progress in Agriculture traditionally occurred through a process of on-farm experimentation, selection and adaptation of traditional landraces[2] of crops. Subsequently this was supplemented by purposive breeding of new varieties of crops, mainly through crossing varieties with desirable characteristics. This process of research was largely conducted in the public sector by national research institutes, supported by a network of international research institutes (http://www.fao.org/ag/cgrfa/IU.htm). Because of the growing concentration in the seed industry, public sector research on agriculture, and its international component, should be strengthened and better funded what will contribute public sector varieties to be available to provide competition for private sector varieties and that the world's plant genetic resource heritage will be maintained**.**The extension of intellectual property protection does carry the risk of restricting farmers' rights to reusse, exchange and sell seed, the very practices which form the basis of their traditional role in conservation and development.

Plants and intellectual property

Until the last century, plants and animals were generally considered to be products of nature. Innovations in crop varieties included introduction of plants or animals collected elsewhere. These did not qualify as inventions but as discoveries. Legal protection of plant varieties was introduced in the United States long before the development of genetically engineered plants. Since 1930 a type of patent introduced especially for Vegetatively propagated plants, known as a "plant patent," has been available from the U.S. Patent and Trademark Office (USPTO) in the Department of Commerce to protect novel clonally propagated (i.e., asexually reproduced) plant varieties including fruit trees, ornamentals, and berries. Since 1970, Plant Variety Protection Certificates (PVPCs) have been available from the U.S. Department of Agriculture. The term of protection offered under a PVPC is now 20 years for most crops, 25 for trees and vines (Wright, 2006). Utility patents can protect novel, non obvious and useful products or processes embodied in tangible forms, for a term renewable up to 20 years. The patent offers protection only within the country where it is granted, including protection (enforceable via lawsuits against infringers) against making, using, offering for sale or importing. Plants containing new genetic material or produced by a novel process might be indirectly protected via a patent on that material or process, as noted by the UK Commission on Intellectual Property Rights (2002, Chapter 3).

The degree of protection provided by the Plant Breeders' Right and by the patent appears to favour the patent. In that sense it is important to reform the Plant Breeders' Right if the objective is not to have it disappear with the profit of the patent. An option suggested by Le Buanec (2006) is to set up one period during which the plant breeders would be committed to not using a plant protected by the Plant Breeders' Right (Buanec, 2006).The assignment of IPRs to living things is of relatively recent origin in developed countries. Protection of plant varieties (or plant breeder's rights - PBRs), a new form of intellectual property became widespread in the second half of the 20th Century.

Patents are widely used to protect the technologies which are employed in research on plant genomics (http://www.nuffieldbioethics.org/filelibrary/pdf/theethicsofpatentingdna.pdf) and patenting of plant varieties is particularly important because, with appropriate claims in the patent, the holder of the patented variety can prevent others from using it for breeding purposes. This is a significant difference from PVP. Proving that a new variety meets the criteria for patentability is more difficult and more costly than obtaining plant variety protection (PVP), where the criteria for protection are lower. Patent protection is also frequently obtained through a broad patent which claims the gene, the vector or carrier for effecting the transformation and so on, which may cover a number of potential varieties or crops incorporating the gene. For practical purposes this may have the same effect as patenting the whole plant, because the patent normally extends to "all material...in which the product is incorporated". Countries may decide to retain lower standards for certain categories of plant in order to facilitate access by nascent domestic breeding industries to PVP protection from which may flow commercial and export benefits (Rangnekar, 2002). Researchers using biotechnology techniques alongside traditional breeding methods will be able to obtain both types of protection as appropriate. These rights are granted by the state to plant breeders to exclude others from producing or commercialization material of a specific plant variety for a minimum of 15 to 20 years. It was implied or specified that certain exemptions were allowed to farmers and researchers (breeders). Such exemptions under PVR systems are termed farmer privilege and breeder privilege (or research exemption).Earlier, patent law was originally considered unsuitable for protecting new plant varieties developed by traditional breeding methods. Therefore several countries introduced special national laws for PVR in the 1960s, as did the International Union for the Protection of New Varieties of Plants (UPOV), established in 1961. This has been broadened under UPOV 1991. UPOV 1978 specified that any member state could provide either patent protection or PVR protection for the same botanical species or genus. The general duration of PVR is 25 years in the case of trees and vines and 20 years for any other variety. There is no longer an implicit right of farmers to save and reuse seed from protected varieties without the breeders' authorisation. If no form of protection is taken, then research results are generally placed in the public domain, mostly in the form of publications, making results available to all without restrictions on use (Das, 2011)

The vast majority of the developing world is far from patenting, although many developing countries are now in the process of implementing new intellectual property protection regimes (Koo et al, 2004).

Some of the cuations in the process of plant variety protection or patenting, that would require an ethical review include: unpredictable or undesirable dissemination of organisms or genes claimed in patent applications that may affect agricultural development and sustainabiity; the acquisition of patent rights that may stimulate the development of technologies that generate suffering of animals or risks to the sustainability of farming practices and agriculture; the patentability of materials discovered in nature, not "invented" by the applicant; patents on genes that cover all possible functions thereof, including those not discovered by the patent applicant; overly broad patent claims such as those drafted in functional terms (covering all ways of addressing a problem), which extend protection to entire species or reach back to parent breeding lines or unimproved germplasm contained in relatives of a patented cultivar; patents covering plant varieties that prevent their use as a source of further varietal improvement; patents over plant materials that restrict farmers' rights to save and re-use seeds in accordance with their traditional practices; the use of border measures in a way that unduly restrains legitimate trade in agricultural products, particularly from developing countries.

Global Research and Development on agriculture is only a little more than half that estimated for health Research and Development. Secondly, there is almost twice as much agricultural Research and Development in the public sector as the private sector. In medicine, expenditure by the private sector is proportionaly larger.. Thirdly, and partly as a result, the developing countries are relatively better served in the case of agricultural research.

http://www3.who.int/whosis/cmh/cmh_report/e/report.cfm?path=cmh,cmh_report&language=english)

Should genetic material identified in nature be patentable on the grounds that isolating and purifying it, differentiates it from an unpatentable discovery? This is a matter for national legislation. The only specific requirement, other than for microorganisms, is that plant varieties be protected and they are required to apply some form of protection, either by patents or a sui generis system.

Apart from the use of patents and PVP, the intellectual property in plants can be appropriated by technological means. For instance, crops such as commercial hybrid maize cannot be reused if hybrid yield and vigour are to be maintained. This characteristic of some hybrids confers a natural form of protection by which seed companies can more readily capture a return on their investment through repeat seed sales. By contrast, other types of seed variety can be replanted each year without deterioration in yield, so that farmers may replant their own seed without repurchasing.

Most of the evidence relating to the impact of patent or plant variety protection on research is from developed countries, and even that is quite sparse. Before IP protection was introduced, private sector breeding initiatives focused on hybrid varieties, particularly of maize, because inherent in these varieties is an element of "technological protection". There was no evidence that total research and development activity had increased as a result of the introduction of PVP, although it appeared to have had some impact on soya beans, and perhaps wheat (Butler and Marion, 1985., Shoemaker et al, 2001).

It has been found that PVP on wheat had not contributed to increased investment in private sector wheat breeding, but may have done so in the public sector. Nor had it contributed to an increase in yields, the share of wheat acreage sown to private varieties had increased markedly, reinforcing the suggestion that the main impact of PVP was as a marketing tool (Alston,A and Venner, R, 2000).

At present there appears to be little evidence that providing patent protection for biotechnology-related inventions is really in the interests of the majority of developing countries which have little or no capability in this technology.

Role of Biotechnology in intellectual property protection

The development of a number of new biotechnologies is based on the discoveries of researchers, which initially provided a problem for potential patentees. A turning point occurred when patent applications involving living organisms began to be filed on a regular basis.The first requirement that a biotechnological innovation has to satisfy, if it is to be patented, is that it constitutes an invention. In this regard a distinction is often drawn between an invention and a discovery, which is considered not patentable. Although there was already a predisposition to regard patenting biological resources as no different from patenting anything else, the decisions of the US Supreme Court in the landmark *Diamond vs. Chakrabarty* case (Bruce and Bruce, 1998) established a principle that "the relevant distinction was not between living and inanimate things but whether living products could be seen as "human made inventions". In the USA this narrow

majority in *Diamond vs. Chakrabarty* laid the foundation for granting intellectual property protection for products of modern biotechnology. Relying on this decision, the United States Patent Office was prepared to grant broad patents for hybridized and genetically engineered organisms. This was part of a major but invisible cultural change, expressed by a senior UK patent expert Crespi (Crespi, 1989).

Significant changes have occurred in both the technology and the structure of research in agriculture. First, the advent of biotechnology, and in particular genetic engineering, in the last twenty years has vastly expanded the possibilities of what can be achieved in agricultural research (for example, introducing new genetic traits in plants). Secondly, while public investment in public research, at least through the CGIAR, has tended to stagnate in recent years, investment by the private sector has gone up rapidly (Nuffield Council on Bioethics, 2002**)**

Breeding is a cumulative science, and seeds accumulate innovations. The number and diversity of innovations utilised in modern cultivar development, and incorporated in the germplasm, can be large. The spread of intellectual property protection on such innovations has meant that germplasm is often covered by a large number of intellectual property claims on these innovations, including key process technologies required to bring about the genetic transformations embodied in the seed. The transgenic vitamin A rice technology, developED as Golden Rice®, is a well-publicised example (Kryder et al., 2000).

To accelerate the plant breeding, the plant breeders increasingly have recourse to the most modern biotechnologies (Drinić Mladenović et al, 2002.,Konstantinov and Mladenović Drinić, 2006., Konstantinov and Mladenović Drinić, 2007., Konstantinov et al. 2010). Technologies that can be mobilised to improve plant breeding conditions are, *inter alia:* genome sequencing initiatives, RNA interference, mutagenesis, the transcriptomic and the proteomic (Fears, 2007. Neither plant patents nor plant variety protection constrain use of varieties for breeding new varieties, with the exception that the UPOV guidelines extend protection to new varieties that are 'essentially derived' from an existing variety. Although not precisely defined, the term is understood to imply that a new cultivar distinguished only by genetic transformation of a protected variety, introducing one or more new genes, would be covered by plant variety protection.

Effective enforcement of patent claims on transgenic crops in other countri is being established. Agreement was reached between Brazil and Monsanto for herbicide tolerant seeds embodying Monsanto's patented herbicide tolerance technology. Soybean producers in southern Brazil agreed to royalty for soybeans collected in the local market, for herbicide-tolerant soybeans incorporating Monsanto's technology (St. Louis Business Journal, September 30, 2005.) Attempts to collect a similar royalty on beans produced in Argentina, where the technology is unpatented, but widely adopted (Qaim and de Janvry, 2002) have met with significant resistance. The fact that foreign competitors do not have to pay what US farmers pay for the Monsanto technology, has prompted US farmers to press for enforcement of royalties overseas (Quam and de Janyry, 2002).

Agricultural biotechnology startups proliferated in the 1980s and 1990s, financed by venture capitalists, often built around patented innovations produced by university scientists in their laboratories, and licensed exclusively to the startup. Non-profit institutions, and their researchers, came to view the returns on their agricultural biotech research in a new light. Transgenic maize and soybean were adopted widely, especially in North and South America, and transgenic cotton has spread to China, Australia, India and Argentina, among other countries (James, 2004).

Remarks

In developed countries the degree of patent protection available to plants and animals *per se* and other life forms varies from country to country, and is usually less strong.

The World Intellectual Property Organization (WIPO) has a lead role in coordination and information collection. It offers an important service in assisting developing counties with implementation of patent systems. Most varieties now in existence, in particular those derived from public breeding programmes, contain genetic material from many sources, often derived from genetic material in gene banks, which themselves may have diverse origins. The major issue of importance to the future of agricultural research is the conservation of genetic resources held in fields and in national and international collections, along with guaranteed access for researchers on terms that recognise the contribution made by farmers in the developing world in conserving, improving and making available these resources.The extension of intellectual property protection does carry the risk of restricting farmers rights to reuse, exchange and sell seed, the very practices which form the basis of their traditional role in conservation and development. Farmers' Rights are not an intellectual property right, but they need to be viewed as an important counterbalance to the rights accorded to breeders in the formal sector under PVP or patents.

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