Review Article

Intellectual property rights and access to agbiotech by developing countries

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Abstract

This review addresses the issue of whether global intellectual property protection regimes are hindering access to agricultural biotechnologies by developing countries. It is assumed that harmonization of worldwide legislation and regulations on intellectual property rights will continue. As such, emphasis is placed on the ways in which developing countries are or should be dealing with these issues. Opportunities arising from an increased availability of information and from little obstruction by patents in the developing world most often do not compensate for the lack of capacity and infrastructure to absorb the technologies. Capacity building is needed in the scientific as much as in the legal aspects of agbiotech in order to take advantage of those opportunities.

Introduction

Long before our time Aristotle gave thought to ways of rewarding inventors. Although the origins of patents and other intellectual property rights (IPR) are not well known, in England the first patents can be traced back to the 15th century. Since then patent law has gone through several iterations reflecting a continuos process of co-evolution with technology and society. Globalization is leading to harmonized IPR regimes around the world, even in the face of stark contrasts in wealth between the highly developed and the least developed nations. IPR is an evolving area with a number of grey zones, causing confusion at all levels, from governing bodies to policymakers and researchers.

During the 1980s, plant biotechnology came of age with the first commercial releases of transgenic crops. Along with commercialization came an increase in IPR protection. Other industries (such as those in the pharmaceutical and the information technology sectors) similarly have gone through this maturation process. However, some new issues have been raised in the case of agbiotech. Some are related to cultural values such as ancestral farmers' rights, traditional knowledge or sovereignty, others address ethical issues such as the patentability of life forms. What makes many people feel uncomfortable about IPR in agbiotech is that agriculture was perceived until now as "the last stronghold of the free". Farmers have had the freedom to replant their own seed and to sell it to other farmers since the dawning of agriculture.

The issue I shall address here is the merit (or lack thereof) of the prevailing perception that patents on biotechnological inventions are preventing the access of developing countries to badly needed technologies in the agricultural sector.

For the purpose of this overview the following definitions apply: 'technology' is the application of knowledge to solving specific problems meeting identified needs; 'technology transfer' is the application of technologies in new geographic or product areas, generally involving adaptation to local needs and conditions (Lesser, 1997). According to Lesser, technology transfer is the means of providing broad access in an interdependent world.

Adoption of agricultural biotechnologies

For many, agbiotech implies genes, genetically modified plants and the processes involved in their production. But other tools and technologies are equally important, including tissue culture, diagnostic tools, molecular marker techniques and bioinformatics.

While holding great promise for the future of agriculture, transgenic crops are not yet playing a major role in most developing countries. Various factors have contributed to this delay, one being that the first generation of transgenics has been geared toward herbicide and insect resistance in crops more relevant to a few developed countries. Another reason is the low level of public acceptance of transgenic crops in many developed countries that are the traditional importers of crop produce from the developing world. This has contributed to a slow development of national biosafety legislation in a number of developing countries and international agreements concerning trade with genetically modified organisms.

First -generation transgenics might not address the needs of smallholders in developing countries, but national economies are also dependent on larger agricultural enterprises and the delay in adoption of these technologies is leading to measurable losses to these countries (Evenson, 2002).

Tissue culture techniques were adopted at a fast rate in developing countries during the 1980s and 1990s, and now they constitute standard technology in areas like banana and plantain production, in the cut-flower industry and in the production of disease-free potato seed. Factors that contributed to its widespread adoption were the low costs of the technology and a quick return on investment because of their direct impact on production.

With restricted funds to conduct and apply research, strategy becomes crucial. Even the adoption of simple technologies can be affected by international competition. Israel, for example, is a fierce competitor in the delivery of *in vitro* multiplied replanting material for banana and plantain in South America. For technology adoption at least two levels of readiness are required, technically trained personnel and strategic management. Without the proper level of quality control, businesses will shop around for the desired product in the global village.

The proliferation of tissue culture laboratories was a symptom of the low cost of the technology. While the production of transgenic organisms or the application of molecular markers in a laboratory represent a steeper price tag they still bear no comparison to the cost of installing a microchip factory or building a pharmaceutical industry from scratch. Only a few emerging economies have managed to create a booming industry based on their own microelectronics industry, especially in southeast Asia.

IPR and agricultural biotechnology

There is something special about IPR and biotechnology, and that is that many biotechnological products and processes are easier to copy than in other areas of technology. Seed can be replanted, genes can be cloned based on sequence information, methods can be copied following established protocols. This makes enforcement of IPR harder to keep up.

The most common IPRs in agbiotech are patents, material transfer agreements (MTAs) and Plant Breeders' Rights (PBRs) (Kowalski *et al.*, 2002). Patents provide the strongest protection for knowhow and genetically modified plants. A patent may protect a process used to obtain transgenic plants as well as the plants themselves and uses thereof. While PBRs are generally the best way to protect individual plant varieties they are not applicable to essentially derived varieties, e.g. a variety into which one gene construct has been introduced by genetic manipulation while maintaining the rest of the genome practically unscathed.

Plants are not patentable subject matter in many countries, although they are in the USA, for example. Signatories of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) are expected to provide IP protection for inventions in all fields of technology (Art. 27 of TRIPs) and that includes genetically modified plants. How this is done in detail is a matter of national legislation and international agreements.

Genetic engineering provides materials and methods to introduce genes into many varieties of one species or into completely different species. In 1998 the Board of Appeals of the European Patent Office (EPO) had to decide whether patents containing claims to processes and products that could result in multiple genetically modified varieties were allowable. At issue was whether there was a loophole in legislation that would allow the patenting of plant varieties, otherwise excluded from patenting according to Article 53(b) of the European Patent Convention. The Enlarged Board of Appeals finally decided that genetically modified plants were patentable subject matter as long as the claims were not restricted to a single variety (EPO case number G 0001/98).

It is also interesting to note that in the context of genetically modified plants the meaning of "essentially derived varieties" had to be reviewed. According to Art. 14 of the 1991 UPOV Act a newly introduced gene does not make a new variety. Therefore, registration of a genetically modified variety requires the permission of the PBR holder. This provides a clearer definition at the interface between patents and PBRs and a further step toward the harmonization of the two IPR regimes (Henson-Apollonio, 2002).

Material transfer agreements (MTAs) are a preferred mechanism for the transfer of tangible property (e.g. cloned genes and plasmids) in countries where IPR enforcement is not appropriate (Kowalski *et al.*, 2002). MTAs are binding legal contracts between the technology provider and the acceptor. The terms of such a MTA can go beyond those established by patents. They can take the form of a first right of refusal to negotiate a nonexclusive license for patents that may result from the data or material provided. In a worst-case-scenario reach-through rights can be imposed through an MTA, i.e. royalties on products resulting from data or material provided in the agreement. In fact, MTAs are the most common legal arrangement by which centres of the Consultative Group on International Agricultural Research (CGIAR) System obtain permission to utilize proprietary biotechnologies (Cohen *et al.*, 2002). This is a risky business, as the centre's role is to distribute the outcome of their research in countries within their mandate, while the responsibility to honour the contract lies with the signatory centre.

In many countries breeding has been traditionally in the hands of government sponsored institutions, but increasingly these activities are being taken over by private enterprises, especially in the more developed countries. This development has led to a strengthening of PBRs. As part of the compliance with the TRIPs Agreement, more countries have become party to UPOV (the International Union for the Protection of New Plant Varieties was created in 1961). New members must adopt the 1991 UPOV Act, to be ultimately adopted by all members, which is more restrictive in matters concerning the free flow of farm-produced seed. Approximately 40% of the UPOV member countries are developing countries or transition economies.

With the recognition of the potential of agbiotech a period of corporate mergers and takeovers ensued, geared toward the control of the whole production chain, from research to the value-added seed and agrichemicals. Family-owned seed companies and small biotech companies were taken over by multinational corporations (MNCs), leading to an oligopoly of the sector. While IPR law was a major incentive to invest, reciprocal infringement brought about by the complexity of the patent landscape was a driver of the consolidation process of MNCs (Barton, 1999). Seed came to be regarded as the ultimate carrier of a substantial investment in R&D. Corporate vision went beyond that of the public sector in terms of investment in agbiotech. The Research Centres of the CGIAR System spend about one tenth of their USD $300 million annual budget on biotechnology, while individual MNCs have funnelled billions of dollars into developing biotech-derived products. These investments are justified by a steady increase in the level of adoption of transgenic crops since their commercial introduction. A substantial acreage of major crops (ca. 20% of the acreage dedicated to those

crops in 2002), mainly in the USA and in Canada, is planted with genetically modified crops.

Although companies are generally more secretive with their research than academic institutions, much of that information is publicly shared through the publication of patents, which must be worded in such a way that a person skilled in the art may reproduce the invention (Art. 29 of TRIPs). This public benefit is part of the *quid pro quo* why countries provide legal IPR protection. Just like any other scientific publication patents can teach us new technologies, contribute to our own research and prevent us from unnecessarily duplicating R&D work. In developing countries where the patents are not in force those teachings can be put to work immediately with freedom to operate (FTO).

Another form of technology transfer are licenses given for humanitarian use, which is a contractual means of segmenting markets and price discriminating that requires an objective case-by-case evaluation methodology (Lybbert, 2002). This variant could be used to develop local crops that provide badly required nutritive factors, for example.

Needs and desirable goals for developing countries

Developing countries are host to farming enterprises of all sizes, many of which are comparable in technification and productivity levels to any farm in developed countries. In the process of North to South technology transfer the requirements are different with respect to both sophistication and to FTO issues. Large farmers are able and willing to pay premium prices for certified seed and also for high-yielding hybrid crops. They also invest in agrichemicals to protect their harvests. Resource-poor farmers on the contrary will rely to a great extent on their own manual labour and seed multiplication to manage their crops.

Major goals for the application of agbiotech in developing countries are to feed the growing and increasingly urban population and to improve the export of traditional and new products in order to boost the countries' economies while preserving the resource base. Modern, increasingly successful economies, rely to a decreasing degree on agricultural exports to support their economies. But for a number of lesser developed countries, self-sufficiency in the agricultural sector would already constitute a major achievement.

Weeds, insect pests and diseases are the causes of major losses in agriculture worldwide. Lack of adaptation to other stresses, such as moisture stress, soil salinity and acidity represent lost opportunities to ensure the livelihood of especially resource-poor farmers in marginal agroecozones. Problems that are more specific to developing countries require a unified effort by the public sector. The scarcity of solutions thus far is the result of a lack of investment over the years and not a failure of biotechnology and probably not of IPR, as many propose.

Is lack of access the culprit?

IPRs do not prevent access to traditional technologies used in plant breeding. The real problem stems from underfunded or non-existent breeding programmes. To deliver efficiently, a good breeding programme should employ state-of-the-art technologies such as marker-assisted selection, anther culture, embryo rescue, and genetic transformation. Only competent, interdisciplinary teams can identify bottlenecks in their programmes and propose entry points for novel technologies to overcome those bottlenecks.

Are IPRs a main bottleneck in technology access for developing countries? In theory there are currently not many restrictions in accessing patented, non-tangible agricultural biotechnologies. We can assert that at present we have the best conditions ever to access knowledge. Thanks to IT and the internet, access to information is blooming, anyone can access scientific information without having to subscribe to expensive journals and the most important patent databases of the world are open for scrutiny as a source of highly valuable information. These open information sources can be seen as a mechanism by which developed countries share their wealth with the rest of the world (Reichman 2002).

Capacity building is required to extract useful information from publicly available data. The Golden Rice™ case is a leading example of the level of IPR complexity involved in the engineering of a single trait: in this case the enhanced production of Vitamin A in a crop plant (Kryder *et al.*, 2000). Golden Rice™ has become a *cause célèbre* in the struggle between the need to protect and motivate creativity and the basic needs of the developing world. Modification of one trait in a plant requires the use of several key steps, from cloning the genes of interest into vectors to transformation using *Agrobacterium* and regeneration of fully fertile plants. Such a process can be swamped by many patents in developed countries, such as the USA with 44 patents, the UK with 35 or France with 37. In developing countries the number can fluctuate between zero and just a few, such as in Indonesia with 6 or South Africa with 5. The situation becomes even more advantageous when we consider that some of these patents will not be enforced by their owners or are not worth enforcing at all.

Today, free access to data is being challenged. Although we are witnessing the proliferation of publicly available information, databases have become major assets in their own right and new statutory protection is emerging, such as the European Union's Directive on the Legal Protection of Databases (Reichman 2002). According to Reichman, this kind of legislation could have serious negative consequences for research in general, hindering scientific collaboration, increasing transaction costs due to increased legal enforcement procedures and the cost of data acquisition, and hampering the quality of research by leading to less data-intensive research.

The ups-and-downs around the sequencing of the human and the rice genomes, where public and private enterprises have been competing to generate and distribute the data, are good examples of these dealings. Companies protect their data as long as they hold commercial promise and there is no public equivalent. Competition by public initiatives can force companies to share their data publicly although funding is not always easy to find in the public domain. Data produced by the private sector is sometimes made freely available for research purposes, although often with strings attached in case commercial products are developed based on the information provided (Niiler, 2000). Such an arrangement may seem attractive in an academic environment, but the consequences to the FTO should be well considered in advance.

IPR harmonization and enforcement and foreign investment

Worldwide harmonization of IPR laws is seen by antiglobalization advocates as a way to impose a domination regime by countries that do most R&D and therefore own most patents, thereby strengthening the monopolies held by MNCs. From the viewpoint of the private sector, protection of the investment is vital to their business. Companies shy away from commercialization of easy-to-copy

products in countries where IPRs are not enforced. An example of how local industries can profit from IPR adoption is the Colombian cut-flower industry (one of the major exporters in the country) which pleaded for a stronger national protection regime to gain access to germplasm developed elsewhere and protected by PBRs.

While many NGOs lobby against the adoption of tougher IPR laws in developing countries, some studies suggest that adoption of PBRs has led to increased private investment, as in the cases of Argentina (Jaffé and van Wijk, 1995) and South Africa (van der Walt, 1994). It is difficult to establish direct links between enforcement of patents and technology transfer but various authors have found lack of enforcement to be a deterrent for foreign direct investment.

Trade partners recognize the need of harmonizing IPR regimes. The European Patent Convention of 1973, which supersedes the European Convention of 1953, currently provides a streamlined patent filing process for 26 countries. The Patent Cooperation Treaty, concluded in 1970 and open to States party to the Paris Convention for the Protection of Industrial Property of 1883, makes it possible to file patents in 118 signatory countries, notwithstanding the fact that patents must enter into the national phase in designated countries to finalize the process. The new Patent Law Treaty adopted by WIPO members in 2000 will further simplify and streamline formal procedures for obtaining and maintaining a patent worldwide when ratified by its members.

Patenting is still not cheap, hence patents are usually registered only in countries where a large return is to be expected from the commercial use of the patented subject matter. Country of manufacture or residence of competitors are additional criteria for filing. Patents applications on key biotechnologies are rarely filed in developing countries, except where major crops such as soyabean, canola and cotton are extensively planted, e.g. Argentina, Brazil, and China.

Out of the 144 World Trade Organization (WTO) member countries, 118 are signatories of the PCT, three quarters of which are developing countries. Through the formation of interest groups within the WTO, developing countries can voice their trade concerns in a much more efficient way than by signing often unfavourable bilateral agreements. In the WTO, trade dispute sanctions for non-compliance are also imposed upon developed countries. IPR law is a main component of trade, as we are witnessing in the ongoing discussion about the production and trade of anti-HIV/AIDS drugs so badly needed in several African countries.

Not only have developing countries had to accept conditions imposed by the TRIPs Agreement but the harmonization process has also had a positive impact on patent legislation in developed countries. In the US, for example, patents used to have a lifetime of 17 years from the date of issue. This allowed for the existence of so-called “submarine” patents in key areas of technology. For strategic reasons and using patent law tools applicants would skilfully extend the prosecution of their applications far beyond the minimum required. By the time the patent “surfaced” (in extreme cases over 15 years later) technology users had become inadvertent infringers and major investments were jeopardised. Unpublished applications of continuations-in-part and divisionals derived from already granted patents also conveyed a misleading feeling of safety. Since 1995 patents in the US enjoy a 20 year term from the date of application. It is now in the interest of the applicant to obtain the grant swiftly in order to be able to exploit the invention within the lifespan of the patent. The new ruling is more consistent with other jurisdictions (Art. 33 TRIPs) and carries the benefits of expediting the process and making it more transparent.

The way ahead for developing countries

In a complex patent landscape, some companies or research institutes might consider moving their research to a country with few patents in the area of their interest. This could be seen as an opportunity to attract investment in R&D to developing countries. If this is done on a large scale and mainly to circumvent product development in countries where IPRs are in force, it could lead to companies taking countermeasures, but as long as the activities are not seen as competing but as a genuine promotion of the country’s livelihood this would not necessarily be the case.

By using South-North trade indicators as a measure of how IPRs could affect developing countries, and contrary to widespread perception, many people would be surprised to find out that there is not too much to be worried about (Binenbaum *et al.*, 2000). The authors in that study made their arguments based on a quantitative assessment of production and trade of 15 crops critical to food security in developing countries and came to the conclusion that most of the production stayed in the developing world. Export crops are few and concentrated to few exporting countries. As stated before, major agricultural industries in developing countries are often in a position to negotiate access to technology.

This reinforces my view that most biotechnologies can be used to address national needs in developing countries with FTO. Moreover, research can be also conducted in exported crops to prepare for the day when the patents in question expire, e.g. expiry of a number of patents on plant transformation technologies will start in three to four years. In the meantime, efforts should be made to strengthen national and regional breeding programmes to maximize the use of agbiotech. Another reason to strengthen research capacity in developing countries is that institutions conducting research on behalf of these countries could be localized in jurisdictions where patents prevent them from carrying out the research.

The fact that a technology is protected by IPRs in a country does not preclude its use unless no licenses are given, exclusive licenses have been granted or licensing costs and/or royalties are prohibitive. Often information about license owners and terms is the most difficult to come by. Exclusivity may in some cases be essential for market positioning, e.g. the combination of a generic herbicide and a crop resistant to it; without protection of the resistance gene the company would lose control over the technology. Other technologies do not or only partially provide a dominant market position to the owner. Such technologies can become a source of income in their own right or at least be accessed through individual contracts that restrict their use to products that do not compete with the interests of the patent owner. An example of such a technology is the gene gun or biolistic technology owned by DuPont.

The gene gun example leads us into another topic, namely how technologies developed in a university environment (Cornell University in this case) can end up being owned by MNCs. Establishing strong links between industry and academia makes perfect sense, as it provides research funds for universities and the results are public good. Public good is used here in the sense that it generates commercial products for the consumer and not of being freely available. In my view, this nexus causes a dilemma only when *key enabling technologies* are sequestered into the realm of inaccessible licenses in one way or another. A field obstructed by too many overlapping patents can lead to an inoperable situation in developed as well as in developing countries. In exceptional situations this has resulted in the past in statutory readjustments, like compulsory licensing provisions, and interventions by antitrust authorities.

There are a number of important activities that stakeholders in developing as well as in developed countries should be pursuing to guarantee access to key technologies. Countries and institutions must become IPR savvy, i.e. they should be in a capacity to analyse their own position with respect to FTO, identify opportunities for the generation of their own IP as a bargaining chip and position themselves in international markets. It is essential that we identify sequestered key enabling technologies made inaccessible through IPR to free those through negotiation or by inventing around if necessary.

FTO in developing countries

Developing countries are usually net importers of technology. While it would be desirable for these countries to become generators of technology, lowering the standards of IPR does not necessarily guarantee improved access to technologies needed for R&D. Without going into legal details we can generalize that there are no experimental use exceptions for the application of protected technologies in jurisdictions where the majority of patents are in force (Nottenburg *et al.*, 2002). In many cases developing countries are legally --but sadly not technically-- in a better position than developed countries to access these technologies, because they are not protected in those countries, hence providing FTO.

FTO analysis is not a trivial exercise. Although patents are public documents, interpretation of patent claims to correctly identify infringement requires legal expertise. Because of commonalities between required agbiotech packages, efforts can be pooled to provide the information cost-effectively. CAMBIA's Intellectual Property Resource for example, provides IPR information services to the R&D community. Its products include white papers describing the IPR situation around key enabling agricultural biotechnologies. Once the FTO situation of sequestered key enabling technologies has been analysed, consortia or international clearinghouse mechanisms with negotiation expertise and capability seem a sensible option to access those technologies (Graff and Zilberman, 2001).

I would like to end this review with an upbeat note. Awareness about FTO issues is growing among all parties involved, industry and academia, the wider research community and end users, patent offices and legislators. Identifying the problem is the first step toward a solution. IPRs were never designed to prevent development but to promote it and thus the process of co-evolution between technology and society will continue. Fine-tuned IPR laws will be instrumental in the acquisition of agricultural biotechnologies for developing countries ready to embrace them.

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