Advancing the Understanding of Biosafety

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Lecture

Patenting Genes and Plants:

Intellectual Property Rights Transform

Research and Agricultural Innovation

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Introduction

Intellectual property rights (IPRs) are exclusive (monopoly) rights granted to an inventor for a limited period of time in exchange for a public disclosure of an invention. Patents are one type of intellectual property protected by national law and are legally enforceable in the country where it has been applied for and obtained. A patent may be granted if it meets the following criteria: new, involves an inventive step and industrially applicable (useful). Minimum global intellectual property rights standards are set by the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), for WTO members to implement nationally. Patents must be available for any inventions, whether products of processes, in all fields of technology. Exceptions for certain public interests are allowed. Under TRIPS, the minimum term of patent protection is 20 years.

Patenting genes and plants

Living organisms were initially not considered patentable subject matter, but that changed with the U.S. Supreme Court decision in Diamond v. Chakrabarty in 1980, which upheld the patenting of a genetically engineered (GE) oil-eating bacterium. Since then, many national laws have opened the possibility of patenting microorganisms, cells, genes and other subcellular components (Correa, 2010). At the same time, Article 27.3(b) of the TRIPS Agreement obliges WTO members to patent microorganisms and to protect plant varieties (by patents, an effective *sui generis* system, or a combination of both). While under the TRIPS Agreement plants and animals may be excluded from patentability; on the flip side this means that they may be patented. A significant number of free trade agreements promoted by the U.S. and the EU have required the expansion of patent protection over biological materials, particularly plants (Correa, 2010). As a result, 'patents on life' have been granted on DNA sequences, genes, cell lines, microorganisms, GE organisms, plants and animals, etc. Such patents reflect the commodification of genetic resources, and the potential monetary returns have provided incentives for 'biopiracy' – the monopolization of genetic resources and associated traditional knowledge taken from peoples or farming communities that developed and nurtured these resources, without their prior informed consent or even knowledge.

What are the implications?

This discussion is focused on the implications of patents on GE genes, seeds and organisms, which have raised several worrying prospects relevant to livelihoods and food security, agricultural innovation, ownership and control of agricultural resources, and research, including biosafety research. The increasing use of these patents is aiding the consolidation of the seed, agrochemcial and biotechnology companies, with food and agriculture increasingly dependent on a small number of powerful multinational corporations (Heinemann, 2009). An example of the vast reach of these corporations is embodied in the Monsanto ownership, since 1996, of the European patent covering all GE soybeans and seeds. This patent was revoked in 2007 after challenges brought by civil society. In that period Monsanto cornered 90 percent of the GE soybean market globally. Such monopolies lead to lower competitiveness, and increased costs for farmers (IAASTD, 2009). Broader still are patents that rely on genetic homologies to claim genetic components of organisms across taxonomic

groups, such as Syngenta's attempt to claim monopoly control of basic gene sequences that regulate flowering and plant architecture in rice. The scope of this patent application was so wide that it extended to other major cereals and flowering plants (Oldham, 2005).

Another aspect of concern is the recent attempt by Monsanto to extend the scope of patents from genetic information to derived products even where such information performs no function (Correa, 2007). Monsanto had sued European importers of soybean meal produced with Roundup Ready seeds in Argentina, erecting barriers to trade to force the Argentine government to impose on farmers a 'technology fee', even though the transgene was in the public domain in Argentina. Monsanto withdrew the suit in 2010 and the European Court of Justice later ruled against the company.

As transgenes are patented, saving GE seeds in countries like the U.S. now constitute a patent infringement and has resulted in lawsuits against farmers for suspected seed saving. As of 26 October 2007, Monsanto has filed 112 lawsuits, involving 372 farmers and 49 small farm businesses, and has won more than $21 million (Centre for Food Safety, 2005, 2007). However, the majority of cases brought by Monsanto have ended in confidential, out-of-court settlements, so the aggressive defence of its patents is not truly reflected. Farmers' rights to save, use, exchange and sell seeds are thus threatened by such patents, with potential food security implications. In many developing countries, farm-saved seed is a large percentage of seed used, reaching above 80 percent for self-pollinated and subsistence crops (Correa, 2010). Furthermore, farmer experimentation is also potentially restricted, curtailing the crucial contribution of farmers to agrobiodiversity and seed development (Heinemann 2009; IAASTD, 2009).

Parallel to the trend of corporate concentration in agriculture is the increasing privatization of agricultural research, with the private sector outspending the entire CGIAR international agricultural research system by 30 times in 2000 (Kiers et al., 2008, cited in Heinemann, 2009). This shift from the public to private sector has various implications on the innovation pipeline, with biotechnology products attracting a disproportionate share of funding. Beyond this, it channels science education and training down certain pathways at the expense of others (IAASTD, 2009). Patents on genes and plants can also become a barrier to access and rapid adoption of new products as they create new hurdles for local research and development (IAASTD, 2009). Moreover, owning the DNA sequence of a gene implies an extension of ownership to the enabling technologies behind, and applications of, this information, e.g. the diagnostic used to identify the gene as a molecular marker in applications such as marker-assisted breeding (Heinemann, 2009). An example from the medical field is Myriad Genetics' patents on the BRCA1 and BRCA2 genes, associated with greater susceptibility to hereditary breast and ovarian cancers, that secured the exclusive right to the diagnostic tests. Myriad's patents were recently ruled invalid, although the company will appeal.

Also of concern are the difficulties faced by biosafety researchers in obtaining samples to conduct independent research on the risk aspects of GE crops, which is needed to ensure that their impacts are properly measured, assessed and understood (Heinemann, 2009; Scientific American, 2009). Twenty-six leading corn insect scientists working at public research institutions in the United States submitted a statement to the Environment Protection Agency in 2009, stating: "Technology/stewardship agreements required for the purchase of genetically modified seed explicitly prohibit research… inhibit[ing] public scientists from pursuing their mandated role on behalf of the public good unless the research is approved by industry. As a result of restricted access, no truly independent research can be legally conducted on many critical questions regarding the technology, its performance, its management implications, IRM, and its interactions with insect biology." (Anonymous, 2009). The warning is "relevant to all transgenic crops and all public-sector scientists of any discipline who seek to conduct research

on transgenic crops" (Sappington et al., 2010). While researchers are expected to seek permission from the seed companies, this is sometimes denied or research agreement terms may include limit or control of publication of the study, while the design and dissemination of the research may be unduly influenced by industry partners (Sappington et al., 2010). An attempt to resolve the issue resulted in a draft set of principles designed to protect the legitimate property rights of companies while affording public scientists independence to conduct research on commercialized transgenic seed (Sappington et al., 2010). It remains to be seen whether this effort will address all the issues, although both sides acknowledge progress. In addition, the increasing involvement of and funding by the private sector influences how research is conducted, raising conflicts of interest issues and questions over biases in results (IAASTD, 2009). Finally, regulatory agencies may also face difficulty in obtaining patented GE materials, for example to detect the presence of transgenes to monitor for contamination.

Conclusion

Significant calls have been made for a reform of the global IPRs framework, and in particular the patent system, also in relation to agriculture (IAASTD, 2009). Within the WTO, there are discussions and proposals for clarification and amendment of the TRIPS Agreement to among others, ensure that living organisms are not patentable and to ensure that any patent applications involving genetic resources and traditional knowledge are accompanied by disclosure requirements. At the national level, there is still considerable space for the design of pro-development intellectual property policies and laws that are sensitive to agriculture interests (Correa, 2010). The recognition of farmers' rights and the contribution of indigenous and local communities to agricultural biodiversity and the elaboration of the Access and Benefit-Sharing Protocol under the CBD are also steps in the right direction.

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