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Tailoring rights regimes in biotechnology; introducing DRIPS next to TRIPS

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Abstract

The debate on tailoring biotechnologies has concentrated mainly on conceptual and technical aspects of the contribution of biotechnologies to development and ways to improve that. One important aspect is however largely debated in isolation and as such has almost systematically been ignored in actual approaches to redesign technologies. This is the impact of rights over these technologies and the materials that are used and produced, and particular in relation to the impact on the legal use of the technologies by the underprivileged.

Tailoring biotechnologies to development objectives has to take into account the rights systems that determine whether, how and by whom the technologies and the derived products (e.g. plant varieties) can be accessed. Different types of rights affect the access to (the products of) biotechnologies by farmers: private rights in the form of intellectual property rights; communal rights in the form of rights on traditional knowledge and other Farmers' Rights, and rights (over genetic resources) based on national sovereignty. These are guided by international agreements, but granted at the national level.

Analysing impact of such rights systems on the application of biotechnologies, and proposing solutions to limitations has to take into account both the regulations themselves and the implementation through licensing strategies. Opportunities exist at both levels to tailor the rights to development objectives. At the policy level, due attention should be given to the Development Related Aspects of Intellectual property Rights, even when the policy space is reduced due to stronger demands from trade negotiations. Examples could be taken from e.g. the European Union. In the field of licensing strategies, examples of broad humanitarian licenses and open source strategies deserve due attention. It appears that such openings in the IPR fields are not being developed in developing countries in the field of genetic resource rights.

Introduction

Many articles in this journal deal with the potential and actual contributions of biotechnologies, including genetic modification to development, notably the reduction of poverty, hunger and malnutrition. Key elements are the empowerment of the poor in the agenda setting of formal research, and the effective linkages of technology in local innovation systems. This is extremely relevant, but one aspect has almost systematically been ignored in the contributions so far; the impact of rights over these technologies and the materials that they use and produce over the legal use of the products of this research by the underprivileged.

We argue that tailoring biotechnologies cannot succeed when the rights regimes accompanying biotechnologies are not tailored at the same time. This article intends to provide an overview of issues involving various rights systems, including private, community and national rights over technologies and genetic resources, being either inputs into or products of research.

This will not go into details of law and country specific legislation. We rather broadly make an inventory of legal bottlenecks to reaching the potential contribution of biotechnologies to the development goals, what options states have in tailoring their legal systems towards development and what opportunities there may be at the implementation level, including institutional policies of public research institutions that support the fulfillment of their roles in this respect.

Biotechnologies - opportunities and risks, and rights and obligations

The biotechnology debate is dominated by genetic modification. Opportunities are framed in terms of widening the genetic base of plant breeding through overcoming natural crossing barriers in plant breeding, and opening the black box of mendelian plant breeding through the use of intimate knowledge of gene identification and functioning, and the unraveling of complex metabolic pathways. Molecular biology can both help in understanding the limiting factors in crop production at the genetic level, and in solving such problems.

Risks are commonly associated with food safety and environmental issues, which indeed are complex scientific problem. This is particularly so when the modified plants are released in smallholder farming systems where the sharing of seed is culturally embedded and the crops enter complex ecologies. This means that once released, such introductions cannot be recalled. However, these are still just scientific problems that can in principle be solved with scientific means.

A potential problem of a different order is a legal one: who owns the technology, and how does that affect the potential impact on the development goals. There are several sides to this question. Most obviously, there is the patent system. Biotechnology introduced the patent system in the plant breeding sector. A court case on a patent application in 1980 on a modified bacterium led to an ever wider interpretation of the patent system in the USA, which now allows the protection of almost any new invention in the sector, including genes, research tools, diagnostics and plant varieties (also when bred conventionally). Many countries followed, except for this last category - almost all countries exempt plant varieties from the patent system and have a softer protection regime instead, called plant breeder's rights or plant variety protection. Patents and other intellectual property rights provide for an exclusive right, i.e. that the right holder can decide on the commercialization of the invention for a fixed time period of time. This is commonly exercised through the granting of licenses to producers or marketing organizations to use the protected subject matter against the payment of a royalty or the provision of other benefits to the right holder. Obligations are few, and mainly involving measures that avoid misuse of the monopoly rights in the market.

Other rights in biotechnology are derived from national sovereignty over genetic resources as laid down in the Convention on Biological Diversity (1992) and communal rights over traditional knowledge, including Farmers' Rights. These rights over the building blocks of biotechnology, the genes and associated knowledge that the biotechnologist uses and tries to understand and manipulate may be called genetic resource rights. Such rights may also lead to a kind of license contracts, called Material Transfer Agreement. Biotechnologists and breeders alike have to obtain prior informed consent over the use of the genetic resources and the contract includes the mutually agreed terms which commonly specify a sharing of benefits. A nation can thus grant access to genetic resources to some and exclude others. The main obligation of the CBD is that the states should conserve their genetic resources and promote their sustainable use.

It is important to note that the various rights systems that the biotechnologist has to deal with 'reach through' to users down the line. Scientists, breeders, seed producers, and finally farmers have to take such rights into account

and are commonly not allowed to share the technologies or the seeds with other scientists, breeders, seed producers and farmers without the consent of the right holder. Rights over biotechnologies thus mean that the advances of science will not easily flow from research labs to application when the right holder has the intention of obtaining benefits (both on intellectual property rights and genetic resource rights). This will involve license negotiations and users who can promise benefits are likely to get a license.

Origins of these rights systems

- IPRs

On the one hand, IPRs have a moral basis, which is laid down in Article 27 of the Universal Declaration of Human Rights: "the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author". The moral grounds date back to the principle of natural law by John Locke that according to Jeremy Betham need specific protection by the state that should secure the inventor a fair share of the reward (Anderson, 2004). Current thought is though that this moral right needs to be balanced with the rights "to take part in cultural life' and "to enjoy the benefits of scientific progress and its applications" laid down in the International Covenant on Economic, Social and Cultural Rights of 1976 (Chapman, 2000).

The economic approach is on the other hand that IPRs are a means to increase welfare in society. Legal rights should provide incentives for inventors and authors to invest in their work and produce useful products or insights. This aspect is reflected for example in the "industrial application" or "use" requirements for new inventions in the patent system. The US constitution: *"Congress . . ... promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries"*. This phrase illustrates that in order to increase welfare, society needs to put limitations to the rights. In this sense, IPRs can be considered a contract between the inventor/author and society (Hardon, 2004) in which the rights are granted under particular conditions, e.g. the obligation to publish the invention for the benefit of the further advancement of science, and for effective use in the public domain after the expiry of the right, and the right of society to retaliate misuse of the exclusive right in the market through compulsory licences.

An important practical argument behind Intellectual Property Rights is that creative products tend to be non-rivalrous and non-excludable (Commission on IPRs, 2002). "Non-rivalrous" means that the consumption by one person does not prohibit another person also using the same product. "Non-excludable" means that others cannot easily be stopped from consuming the product. This is particularly true for biological products like genes and plant varieties that are self-replicating through seeds.

The balance between the rights of society on the one hand and those of the right holder on the other is very difficult to determine and subjective. Davis (2004) questions whether the current IPRs contribute to a social optimum in research and development (R&D). Andersen (2004) critically discusses the different economic arguments from a costs and social benefits perspective: there are administration and enforcement costs, monopoly or anti-competition costs, opportunity costs in depriving others from using the most effective solutions, which is specifically aggravated by the broad scope of patents, social costs by increasing the cost price of products through royalties, and finally costs that are incurred when patents divert investment in socially less productive channels just because protection can more easily be obtained in certain fields. This latter argument may be particularly relevant in plant breeding in developing countries, where significant social benefits can be derived from access to good varieties by the poor.

IPRs in agriculture have been irrelevant in developing countries until very recently. The WTO Agreement on Trade Related Aspects of Intellectual property Rights (1993) requires all members of the trade organisation to develop IPRs in their national laws. More recently, the requirements of trade agreements between the US or EU on the one hand and developing countries on the other significantly increase the strength of the rights compared with the minimum standards of TRIPS (GRAIN, 2004). Trade benefits are a great incentive for countries to accept these strong IPRs even though they themselves may not optimally serve development goals.

- Genetic Resource Rights

The perception that plant species can be a strategic resource developed in the early colonial period when the emerging global powers were keen on containing valuable crops within their colonies (Plucknett et al., 1987). In more recent days there have been formal (Smale & Day-Rubinstein, 2002) and informal (Fowler & Mooney, 1990) embargoes on the export of genebank

materials of crops. However, among farming communities the concept of free exchange is commonly held high.

The different values of genetic resources (Brush, 2000; Birol, 2002; Smale, 2006) and the realization that diversity eroded (Harlan & Martini, 1936; Bommer, 1991) triggered international debates about the conservation and availability of genetic resources in the agricultural sector in the late 1950s (Esquinas-Alcazar, 2005). This debate came to the conclusion that genetic resources are a heritage of mankind. The "enormous contribution that farmers of all regions have made to the conservation and development of plant genetic resources, which constitute the basis of plant production throughout the world" was internationally recognised in the voluntary International Undertaking on Plant Genetic Resources for Food and Agriculture (IU PGRFA: http://www.fao.org/ag/cgrfa/IU.htm). This recognition was the basis of the concept of Farmers' Rights, "vested in the International Community, as trustee for present and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuation of their contributions".

The debate on biodiversity in the environmental sector culminated in the UN Conference on the Environment and Development in 1992. Through its (binding) Convention on Biological Diversity (CBD), biodiversity became a natural resource under the sovereignty of nations. Parties may set conditions to access to genetic resources and make it subject to agreed terms that provide for prior informed consent and which may include some form of benefit-sharing. Countries are free to negotiate and design such bilateral access agreements. The CBD thus explicitly overrode the "heritage of mankind" principle of the IU PGRFA. The special nature of agricultural genetic resources (Stannard et al., 2004) and the vast numbers of exchanges led to a multilateral system of access and benefit sharing for a number of major crop species under the International Treaty on PGRFA (2004). This Treaty also spells out the Farmers' Rights as the right to protect Traditional Knowledge, to benefit sharing, to participation in decision making at the national level, and it refers to the right of farmers to save, use, exchange and sell farm-saved seed. This concept thus links with both the CBD (benefit sharing) and the debate within the World Intellectual property Organisation (WIPO) on traditional knowledge in relation to genetic resources and folklore.

-Rights on Indigenous and Traditional knowledge

An international agreement has not been concluded on the protection of the rights on indigenous and traditional knowledge (ITK). The Intergovernmental

Committee on genetic resources, Traditional Knowledge and Folklore of WIPO is debating ways and means of protecting such rights. It is, however, difficult to determine whether such rights should be exclusive rights, equivalent to IPRs or based on recognition and benefit sharing only. The first option creates tensions because IPRs are meant to take innovations to the public domain (e.g. patent rights expire after 20 years), whereas such a temporary protection would not recognise the contribution of many generations in the generation of ITK. Secondly, the governance of such community rights needs to be clear, particularly to what extent members of the community who emigrated to cities or other regions would retain their involvement and rights to benefits. Making ITK protection an exclusive right could severely limit access by the global community to such knowledge, particularly when the exploitation of such rights might most favourably be exploited through the patent system. The limitation to recognition and benefit sharing has the risk that benefits may be small and that it will be easy to 'patent around' the ITK.

The debate on ITK is very relevant for biotechnology, but particularly to its uses in pharmacology and other industrial applications. Whereas medicinal knowledge is often kept secret in the community and handed from healer to the next generation, ITK in agriculture is commonly shared among all farmers in the community (and beyond). This means that exclusive strategies are extremely difficult to apply.

Impact of these rights systems: confusion and hyperownership

Even though the international agreements may be legally coherent, inconsistencies arise at the implementation level when the requirements are to be translated in national law that affect seed systems. The main reason is that they are based on unrelated goals in the agricultural, environmental and trade sectors (Leskien & Flitner, 1997; Drahos & Blakeny, 2001; Sampath & Tarasovsky 2002). Where the CBD grants national sovereignty over genetic resources and promotes the rights of local and indigenous communities over their genetic resources and associated knowledge, TRIPS has the effect that individual IP-holders obtain control over particular genetic resources and technologies. Similarly, there is conceptual tension between the national sovereignty principle of the CBD and the multilateral approach of the International Treaty, between the promotion and the 'taxation' of intellectual property rights in TRIPS and IT PGRFA respectively, and between private IPRs and communal rights over traditional knowledge. Finally, the concept of Farmers' Rights collides with intellectual property rights principles. (Louwaars & Visser, 2004).

Another outcome of the negotiation processes is that although the different parallel discussions are not linked, still they do appear to influence each other, unfortunately not to reach an agreed optimum of rights over genetic resources and associated knowledge for individuals, communities and nations (Louwaars, 2006). Butler et al. (2002) claimed that strong breeder's rights have resulted in claims for Farmers' Rights. Safrin (2004) in turn called the outcome of this process 'hyperownership' a term that describes the reduction of the public domain or, as she describes it, 'the legal enclosure' of genetic resources through a spiral of increasing levels of both intellectual property and other genetic resource rights. Gepts (2004) confirmed in turn that the commoditization of biodiversity has led to the active pursuit of IP protection on genetic resources (both in agriculture and pharmacology), leading to claims of biopiracy when appropriation is achieved without authorization, and in turn to tighter rules. Similarly, 'thickets' of intellectual property rights create barriers to access to technologies and genetic resources (Bobrow & Thomas, 2001) and increase costs (Barton, 2000).

Tailoring rights

Regulatory frameworks should not be seen as a fixed 'given externality'. Intellectual property rights systems have shown to adapt to changing situations. Most changes in the patenting of life forms since the Chakrabarty case in 1980 are the result of new interpretations of existing law. This high level of dependence of the IP-system on judiciary rather than on democratic processes and the importance of case law is an excellent way to respond to the quick technological developments. Even though the general trend during the last decades has been to gradually strengthen the rights of the inventor, also clear indications can be observed that there is a way back - or 'a better way forward'.

The plant breeding sector has always been a good example of the flexibility of IPR systems. Plant varieties have been exempted from patent protection all over the world until in 1985 in te USA and soon after in Japan and Australia it became possible to apply for patents. Instead, plant breeder's rights systems were developed that are more in line with the culture and practice of farming through some important exemptions. Breeders are allowed to use any protected variety for further breeding without permission of the right holder (which would not be possible under patent regimes) and farmers are allowed, within certain restrictions, to multiply the seed for their own use and in some countries also for exchanging and selling to other farmers. The patent system doesn't normally provide opportunities for such exemptions.

The patenting of genes and other components of plant varieties, which is possible in Europe, would create ambiguity since farmers would be allowed to save seed under the breeder's rights system, but not when a component is patented; and a patent holder could control not only the gene but the whole genetic background if other breeders would not be allowed to use the variety in further breeding (Louwaars, 2007). Recent decisions by Germany and France to apply the exemptions also to varieties with patented components is both an excellent example of how developing countries would create openings in the patent system, and proof that a legal system like IPRs is not cast in stone. Another important example is the decision that put a halt on the patenting of expression sequence tags (ESTs), strands of DNA that do not have an apparent function (Kintisch, 2005). This decision followed an unprecedented run on patents as a result of the first sequencing work in the early 1990s.

At a more general level, the development of WIPO may provide additional grounds for opening up the patent systems in many developing (and industrialized) countries (Gerhardsen, 2007). Finally, the adoption of the International Treaty can also be considered a 'better way forward' within the general framework of the CBD, for example by improving access and reducing transaction costs for many major food and feed crops.

An important trend that runs counter to the possibilities to tailor rights regimes to the development needs of a country is international harmonisation of rights and systems. IPRs and genetic resource rights are territorial and based on national law. Harmonization intends to results in transparent rights across borders and to reduce transaction costs, thus facilitating international trade in innovations and goods derived from these. It is therefore logical that the push for international harmonisation of laws is mainly based on the trade agenda. However, the trade-related aspects referred to in the TRIPS Agreement are only one group of aspects relevant to rights over genetic resources. In the implementation of TRIPS and in negotiating the Free Trade Agreements it is insufficiently realized that the primary reasons to introduce intellectual property rights are related to stimulating investments in innovation. When developing countries would be allowed to make the development-related rather than the trade-related aspects of intellectual property rights (DRIPS) leading, they would come to very different approaches, with more space for specific rules to deal with country specific objectives and a more detailed approach (Shen, 2005). Such approaches would benefit from harmonisation of implementation systems, such as joint examination of patent applications in the PCT system (Patent Convention Treaty) or standardised variety testing procedures devel-

oped by UPOV. The World Bank calls for differential rights for commercial (export) crops and subsistence crops in the scope of protection of varieties (World Bank, 2006), which is an explicit example of tailoring rights to the development needs of a sector. The conclusion of the IT PGRFA may be considered in the same line - its multilateral system is then a specially designed system to facilitate access and benefit sharing for major food and fodder crops.

Tailoring implementation strategies

IPRs and genetic resource rights provide rights; it is the way that they are exercised that determines their effect on farming. For example, the CBD provides national sovereignty on access to genetic resources that give states the right to make access subject to terms. The Nordic countries in Europe use this right to make their genetic resources widely available without asking for monetary benefit sharing (Evjen, 2003), whereas the countries of the Andean Community consider genetic resources and important national heritage that need to contribute to development (Louwaars et al., 2006a).

Similarly, there are ways to use the patent system for making technologies widely available to the public. Patent holders may offer so-called humanitarian use licenses for the use of their protected technologies for development. This requires extensive negotiations, but these regularly lead to liberal offers by patent holders that not only include a freedom to use the technology but also training to use it properly and effectively. The greatest challenge for researchers in developing countries is to know who the owners are, and then to get them to negotiate. Organisations have been established to mediate in this field and to reduce transaction costs, e.g. AATF (www.aatf.africa.org) and ISAAA (www.isaaa.org). This shows the weaknesses of depending on such licenses: few transactions are actually concluded and this requires a good knowledge of IPRs, liabilities and contract negotiations.

A second step in this direction has been taken by the Generation Challenge Programme that developed a standard licensing agreement for all partners, which automatically makes technologies available for use for the benefit of the poor in developing countries (Barry & Louwaars, 2005). If such language could be accepted as a standard it could be used much more widely. An important limitation to such approach is the recent introduction of liability clauses in the Cartagena Protocol, which puts a significant responsibility to the developer of a technology on problems that arise out of its use (Sullivan, 2005). The result of this decision is that technology providers are less likely to accept

broad licenses which mean that they don't have control over the use of their technologies.

The third step is the creation of open-source licenses for biotechnologies. This idea is particularly pursued by the Biological Information for Open Society (BIOS) initiative (Nature, 2004).This approach is built on the development of open-source biotechnologies, similar to methods used in software (e.g. Linux) and copyrighted text materials (Creative Commons, CopyLeft). The scientific basis will be provided by new transformation technologies developed by CAMBIA (Broothaerts, 2005; Constans, 2005) based on microbial processes other than those mediated by *Agrobacterium tumefaciens* on which hundreds of patents rest. The open-source concept uses patents to make sure that the information can be licensed freely to all, with only one major condition, i.e. all users of the patent will provide the same liberal access to all subsequent inventions derived from it. It remains to be seen how this concept may work in biotechnology where many scientists will use additional proprietary technologies in trying to expand upon the open source potentially creating barriers to the grant-back obligation. BIOS also operates a database with information from over 70 patent offices, which facilitates initial analysis of IP by researchers (see www.cambia.org).

Unfortunately, the discussion on increasing the public domain is ongoing in the field of IPRs and not in genetic resource policies (Louwaars, 2006). It is high time that the proponents of strict access regimes to genetic resources consider exclusions for the use of the resources for development objectives (both in agriculture and health).

The decision to patent or not, or to commercially license or provide free access is made by the rights-holder. This can be the individual researcher or in most cases, the organisation that employs the inventor(s). Institutional policies thus determine to a large extent whether the rights indeed create blockages to innovation downstream. Such policies are particularly important for public research and education organisations. IPRs are designed to create benefits in the market and are particularly designed to support commercial investments in R&D. Public research institutions thus have to decide to what extent they want to commercialise products and whether a focus on markets is in conflict with their public task. A watershed decision in this respect was the Bayh-Dole Act in the USA which allowed or even promoted public universities to protect and commercialise their inventions.

Claims have been made that access to information is delayed after policies were introduced at universities in the USA to seek protection (David, 2004);

access to technology was also considered reduced (Zheng et al., 2006); secrecy and the use of patents as blocking tools disturbed public research (Cohen et al., 2000), start-up companies were hindered (Wright et al., 2006), and the role of lawyers in research significantly increased (Maurer et al., 2001). This decision has thus contributed to the "anti-commons" (Heller & Eisenberg, 1998) that according to Runge and Defrancesci (2006) may lead to socially suboptimal access to the resource and inhibit innovation and development. An analysis of the impact of the Bayh-Dole Act (Rosenberg & Nelson, 2004) indicates that as a result of the high costs of managing IP, very few schools make a net profit.

Also in developing countries the question is relevant. Louwaars et al. (2005) report that reduced public expenditure in agricultural research is a major reason to embrace IPRs as a revenue-maker, but also the expectations of public-private partnerships in agricultural research. Some respondents in their research realise that this approach will have impact on the research priorities. Focusing on revenue likely leads to an increased focus on profitable crops (like hybrids and market crops) and commercial farmers (Louwaars et al, 2006b). When public policy also intends to use agricultural research for poverty reduction, agro-biodiversity management, and rural food security strategies, such institutes may have to deal with IPRs differently.

Conclusions

Tailoring biotechnologies to development objectives has to go hand in hand with tailoring of the rights systems that determine whether, how and by whom the technologies can be accessed. Such aspects should be taken into account throughout the technology development process, from priority setting and design of research methodologies and programmes to the (further) dissemination of products. This aspect has been under-investigated in the literature on tailoring biotechnologies.

Different types of rights affect the access to (the products of) biotechnologies by farmers: private rights in the form of intellectual property rights; communal rights in the form of rights on traditional knowledge and other Farmers' Rights, and rights (over genetic resources) based on national sovereignty. These are guided by international agreements, but granted at the national level.

Analysing impact of such rights systems on the application of biotechnologies, and proposing solutions to limitations has to take into account both the regulations themselves and the implementation through licensing strategies.

Opportunities exist at both levels to tailor the rights to development objectives, and where policy space is reduced due to stronger demands from trade negotiations, openings are forged through private and NGO initiatives. It appears that such openings are not being developed in developing countries in the field of genetic resource rights.

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