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Intellectual Property Rights in Plant Biotechnology: A Contribution to Crop Biosecurity

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Abstract: This contribution reviews the different forms and scope of intellectual property rights relevant to crop biosecurity; the genetic assets and commitments made by developing countries under the TRIPS agreement and the alternatives open to them. The potential positive and negative consequence of introducing and strengthening IPRs for the transfer of technology and innovation in developing countries with special reference to crop biosecurity is highlighted. Furthermore, relevant viewpoints to the debate on access and benefit-sharing of the global plant genetic resources, genetic erosion and biopiracy that are of significance for crop biosecurity are provided. Consequently, governments should consider formulating internationally compatible laws, standards and practices regarding plant materials and data such that crop protection and biosecurity as well as the ethical handling of biological materials and data from plants can be guaranteed.

Introduction

The impact on developing countries of strengthening the IPRs as a result of the Uruguay Round TRIPS Agreement on genetic resources is a sensitive issue at the centre of a polarized debate. Loss of biodiversity is the major global threat to the planet other threats being climate change and agrochemical pollution. Fears have been expressed that genetic resources originating in developing countries will be used for the development of new agricultural biotechnology based techniques and products by the industrialized countries, and to which biotechniques and bioproducts access would subsequently be restricted by IPRs. Also, it is argued that strengthened intellectual property rights would increase the flow of

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technologies and products from developed to developing countries, and would provide new incentives for local research and innovation.[1]

The consequences of strengthened IPRs for the crop biosecurity regime are likely to be uneven and differing among countries which have varying levels of development in plant biotechnology and capacities to stimulate innovation in agriculture. Impacts are also likely to vary from one crop to another, between commercial and food crops and amongst different groups of farmers.

The genomics revolution, however, has provided an additional impetus to the debate about IPRs for crop safety and biosecurity. Most of the more advanced countries are expanding both their own technology base by developing and importing new biotechnologies. Some countries in Asia, Africa and Latin America are attempting to develop biotechnologies specifically directed to solving their agricultural problems through publicly funded national agricultural biotechnology research systems. Most developing countries, however, have not yet reached this stage in the development of agricultural biotechnology due to many tangible and intangible reasons in their research and development systems and their under-developed market infrastructure.[2] If developing countries are to benefit from the use of modern biotechnology in agriculture and want to increase the status of crop biosecurity then the key constraints such as bioterrorism and biopiracy, etc., within the research, technology development and delivery system need to be clearly identified with the introduction of appropriate policy measures.[3]

Intellectual Property Rights (IPRs) and Crop Biosecurity

IPRs can be defined as a set of laws devised for the purpose of protecting or rewarding inventors or creators of new knowledge. Precisely because knowledge, unlike consumable goods, can be shared by any number of persons without being diminished, creators are dependent on legal protection to prevent direct copying or the utilization of the product or process they have invented without the payment of compensation. IPRs are thus intended to confer exclusive rights for inventors or discoverers, for a fixed period of time.[4] Biological materials and data have long been preserved in and disseminated by repositories of microbial culture collections, seed banks, etc and were a source of crop biosecurity. These biological collections face great challenges but also great opportunities owing to the explosive increase in biological materials and data in the field of crop safety and biosecurity.[5]

The fact that the richest nations are home to the smallest pockets of biodiversity while the poor are stewards of the richest resources underlines the interdependency of all nations and the urgency of formulating common strategies for sustaining biodiversity, eliminating biopiracy and genetic drain and ultimately ensuring crop biosecurity.

A biosecurity guarantee attempts to ensure that ecologies sustaining either people or animals are maintained. Crop biosecurity is the maintenance and conservation of crop biodiversity, checking the threat of bioterrorism, judicially and wisely using crop genetic diversity for crop improvement, reducing the risk of biopiracy and genetic erosion, and protecting the crops from other hazards such as insect pests and diseases for the welfare of humankind.

Forms of IPRs

There are different forms of IPR that play a key role in crop biosecurity and which are as:

Patents: A patent is an exclusive right granted to an inventor. Once issued, a patent gives the inventor the legal right to create a limited monopoly by excluding others from creating, producing, selling or importing the invention. This right is of limited duration, for a minimum period of 20 years from the date of filing the patent application. In exchange for the right of exclusion, the inventor must disclose all details describing the invention, so that when the 20-year patent right expires, the public may have the opportunity to develop and profit from the use of the invention.[6]

The patent system has many objectives. It aims to protect inventors; promotes the disclosure of inventions, as against secrecy, through the publication of patent applications; and to stimulate others to "invent around" patents in devising new solutions to technical problems. Therefore, insofar as a patent gives its holder the exclusive right to benefit from his/her particular solution, others may be induced to find alternative solutions which can be used without infringing the patent in question. The granting of a patent is subject to the fulfillment of three conditions:

- Usefulness or industrial application
- Newness or novelty, in the sense that the invention was not previously known to the public; and
- Non-obviousness, or inventive step, so that the invention constitutes an acknowledged extension of prior knowledge.

International Convention for the Protection of New Varieties of Plants (UPOV): The UPOV Convention was signed in 1961; entered into force in 1968; and was then revised several times, in 1972, 1978 and 1991. This Convention allows countries to protect plant variety by patents.

Plant Breeders' Rights (PBRs, or Plant Variety Protection (PVP): The PBRs allows for the protection of new plant varieties for a term of 20 years (25 for tree crops). A country can develop its own system of protection, referred to as a *sui generis* system, i.e. a system of rights designed to fit a particular context and need that is a unique alternative to standard patent protection.

Geographical indications (GIs): GIs identify the specific geographical origin of a product, and the associated qualities, reputation or other characteristics and usually consist of the name of the place of origin. For example, food products sometimes have qualities that derive from their place of production and local environmental factors. The geographical indication prevents unauthorized parties from using a protected GI for products not from that region or from misleading the public as to the true origin of the product.

Trade Secrets: These consist of commercially valuable information about production methods, business plans, clientele, etc. They are protected as long as they remain secret by laws which prevent acquisition by commercially unfair means and unauthorized disclosure.

Database Protection: The EU has adopted legislation to provide *sui generis* protection in respect of databases, preventing unauthorized use of data compilations even if non-original. Exclusive rights to extract or utilize all or a substantial part of the contents of the protected database are granted.

Over the last two decades there has been an unprecedented increase in the level, scope, territorial extent and role of intellectual property (IP) protection in crop biosafety and biosecurity which include the following trends:

— The patenting of living things and materials found in nature, as opposed to man-made products and processes more readily recognizable to the layman as inventions.

- — The modification of protection regimes to accommodate new technologies (particularly, biotechnology and information technology).
- — A new emphasis on the protection of new knowledge and technologies produced in the public sector.
- — The focus on the relationship between IP protection and traditional knowledge, folklore and genetic resources.
- — The geographical extension of minimum standards for IP protection through the TRIPS agreement and of higher standards through bilateral and regional trade and investment agreements; and
- — The widening of exclusive rights, extension of the duration of protection, and strengthening of enforcement mechanisms.

Crop Biosecurity

Contributions of International Agreements on Crop Biosecurity

During the last three decades, there have been numerous meetings and consultations at the international level for streamlining the availability and utilization of existing biological resources in an equitable manner. This has been necessitated by revolutionary developments in the life sciences and possibilities of generating immense economic benefits. This situation is in contrast to the era of the Green Revolution when all the germplasm developed was easily available throughout the world and many developing countries greatly benefited from it. At that time no issues regarding IPRs were raised. However, now that the world situation has changed with the 'free market economy' as the dominant force, agriculture is viewed as an industry or business subject to all the regulatory measures. It is in this context that agriculture figures prominently in all the deliberations of the World Trade Organization (WTO) wherein various aspects have been strongly contested between countries of different blocks with different interests. The main international agreements that impact on IP for crop biosecurity are as follows:

WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The TRIPS Agreement, adopted in 1994, requires that 'patents shall be available for any inventions, whether products or processes, in all fields of technology'. However, it allows countries to exclude from protection 'plants and animals other than micro-organisms'. It does require that countries provide for the protection of plant varieties either by patents or by an effective *sui generis* system (i.e.PVP) or both. The TRIPS Agreement permits countries some flexibility in the precise form and the extent of protection and promotes the fundamental idea of extending IPRs to agricultural genetic resources. The general objectives of the TRIPS Agreement are the protection and enforcement of IPRs, the promotion of technological innovation, and the transfer and dissemination of technology. A WTO member country must be non-discriminatory and extend the same treatment to all other members that it affords one member. Most developing countries are opposed to the use of patent systems in agriculture.

Objectives of the TRIP's Convention

The broad objectives of the convention are the conservation of the biodiversity, the sustainable use of the components of genetic resources like crops, forest plants and animals and the fair and equitable sharing of the benefits arising out of the utilization of generic resources.[7]

All the commitments such as general measures for conservation and sustainable use, *in-situ* and *ex-situ* conservation and sustainable use of the components of biological diversity, access to genetic resources, access to and transfer of technology, handling of biotechnology and distribution of benefits and financial mechanisms are governed by objectives that are interrelated to each other.

Article 6 obligates contracting parties to develop and adopt a national strategy for the conservation and distribution of benefits, sustainable use of biological diversity and also to integrate the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies. This should be done in accordance with each party's peculiar conditions and capabilities.

Article 6 provides the basis for *Article 10* which contains more concrete provisions related to national strategy and commitments to avoid or minimize the adverse impact on biological diversity, and to protect and encourage customary and traditional culture.

Contributions of TRIPs Agreement towards Crop Biosecurity

The TRIPs Agreement under the *Article-27.3 (b)* imposes on all Member States the introduction of plant variety protection either through patents or an alternative *sui generis* system. However, there has been constant pressure on developing countries to choose plant breeder's rights as an alternative to patents. Both patents and PBRs are monopoly rights, which seem to allow the private sector to enter the seed business. Though, the scope of *Article-27.3 (b)* is under review of the WTO, the Third World is working hard to exclude naturally occurring materials, and genes from the patent process. Presently, the plant breeder's right is protected within the framework of the TRIPs Agreement It made a compulsory exception to breeder's rights in favour of farmers; strengthened the preview of PBRs by introducing a registration system, and recognized the complete monopoly right of the breeder on plant variety. IPRs under the TRIPs Agreement are perceived as a private right. TRIPs do not recognize community intellectual rights or collective intellectual rights. The concept of collective and community intellectual right is essentially a Southern concept. The Northern industrialized societies are opposed to this concept.

Therefore, TRIPs represents the Northern view of IPRs. Moreover, the patent regime under the TRIPs failed to respond to the shift in innovative activity, from tangible entities to intangible entities like DNA and microorganisms. TRIPs replicates the old patent jurisprudence over all type of innovations which makes it possible to get a patent for plants and microorganism without having the real innovative element. Moreover, it resulted in the taking away of genetic materials from South to North without adequate compensation for either innovation or maintenance of those materials in their native places. The major effect of this TRIPs-sponsored commercialization is the depletion of biodiversity. Therefore, the moot question is how the biodiversity and traditional knowledge could be protected by negotiations under the CBD from the onslaught of biopiracy.

The Food and Agriculture Organization (FAO) Commitments for Crop Biosecurity

In order to protect the farmers' right on plant variety a revision on the "International Undertaking on Plant Genetic Resource" is being negotiated within the FAO Commission on Genetic Resources. The proposed revision recognizes the protection of traditional knowledge, the right to participate in sharing the benefit that arises from the use of plant variety, and the right to participate in decision-making concerning their management. The revision also recognizes that, no limit should be put on the farmers' rights to sale, use and exchange of seeds including every right over what they have produced. On the issue of protection of bioassets, the FAO undertakes to protect the farmer's right that is contrary to *Article-15* of the Convention on Biological Diversity (CBD) which recognizes the sovereign right of the state on biodiversity.[8]

Convention on Biological Diversity (CBD)

The idea of an umbrella convention addressing the whole gamut of biodiversity first emerged at the Third World National Parks Congress in Bali, Indonesia, 1982. Notwithstanding that United Nations Environmental Programme (UNEP) had established an adhoc working group in 1987 to decide upon the necessity of such a convention.

Like many other international negotiations this also turned into a North-South debate, which on this occasion was between the technology-rich North and the resource-rich South. However, since the technology of the North depends on the South's resources, the Northern countries need a conducive international legal regime to assure raw material supply for their biotechnology-oriented agrofertilizer and pharmaceutical industries as well as a new legal regime in harmony with the evolving international trade regime under WTO. Moreover, the developed countries are not ready to change their development paradigm for biodiversity conservation. The South on the other hand wanted to exchange their resources with technology from the North for agriculture. To achieve these goals both groups had heated debates on access to genetic resources, transfer of technology, biosafety, biosecurity and financial mechanisms for conservation.

International Treaty on Plant Genetic Resources for Food and Agriculture

This treaty, which entered into force on 29 June 2004, focuses on agricultural genetic resources — access to and sharing of the benefits derived from them. The treaty is concerned with preserving the genetic resources developed by poor farmers and maintaining access to agricultural genetic resources for international public research. All countries are required to meet their obligations under these agreements and as such may need to amend, update and/or draft IP legislation. Technical and legal assistance and support for capacity building in these areas are also required to facilitate national policy development. The WTO's emphasis on science-based regulatory standards as in the area of biotechnology will require a strengthening of the underlying scientific capacity of the developing countries. Access to technological developments such as biotechnology and collaboration with public or private sector institutions in other countries, such as the US, Europe or Japan, require an understanding of and the capacity to manage intellectual property in order to encourage investment and ensure benefit sharing through cooperative agreements.

Given the limited resources, what then should be done to build the underlying scientific and technical capacity to contribute to the policy dialogue, development and implementation of IPR, to ensure the effective participation of scientists in international negotiations, and simultaneously, to enhance their contribution to developing national systems to protect and support crop biosecurity.

Article 8(g) of the CBD, signed by 156 countries upon its publication in Rio de Janeiro in June 1992, commits the parties to "establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology..."

Article 8(h) commits the parties to "prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species."

Article 19(3) commits the parties to "consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology

IPR and Developing Countries

The task to consider is how and whether IPRs could play a role in helping the world meet the targets of crop biosecurity – in particular by reducing poverty, helping combat crop diseases, enhancing access to crop biodiversity, contributing to sustainable development; and in identifying and removing obstacles in meeting those targets. Some argue rather strongly that IPRs are necessary to stimulate economic growth, which, in turn, contributes to poverty reduction through crop biosecurity. Stimulating invention and new technologies leads to increases in agricultural or industrial production. Hence these proponents of IPRs are of the view that there is no reason why a system that works for developed countries could not do the same for developing countries. Others argue with equal vehemence that IPRs rights do little to stimulate invention and research in developing countries since the necessary human and technical capacity may be absent; and moreover the poor will not be able to afford the products, even if developed. IPRs limit the option of technological learning through imitation, allow foreign firms to drive out domestic competition by obtaining patent protection, and to service the market through imports rather than through domestic manufacture. Moreover, IPRs increase the costs of essential medicines and agricultural inputs affecting poor people and farmers rather badly.[9]

In the past three decades as mentioned earlier, the developing nations of Asia had been a major beneficiary of agricultural technologies that totally changed the landscape of Asian agriculture. Higher productivity gains were achieved with the wave of technologies such as high yielding variety seeds, chemical inputs, irrigation, and improved cropping systems. By the year 2050 more than 5.8 billion people (65 per cent of the world population) are estimated to exist in Asia. To meet the demand for food and feed over the next 25 years, cereal production has to increase by 50-75 per cent.[10] Currently as well as in the future this remains an imminent problem of concern.

Apparently, the biological limits of current plant types and varieties developed through conventional breeding have reached a plateau. There is limited scope for extending the land area used for production. Thus, increased food production has to be generated from productivity gains through increase in yields by judicious use of plant genetic resources. In assessing these opposing arguments, it is important to remember the technological disparity between developed and developing countries. Low and middle income developing countries account for about 21 per cent of world GDP, but for less than 10 per cent of worldwide research and development (R&D) expenditure. The developed countries spend far more on R&D than developing countries. Almost without exception, developing countries are net importers of technology.

Developing countries are not a homogeneous group, a self-evident fact that is often forgotten. Not only do their scientific and technical capacities vary, but so also their social and economic structures, and their inequalities of income and wealth. The determinants of poverty, and therefore the appropriate policies to address it, will vary accordingly between countries. The same applies to policies on IPRs. Policies required in countries with a relatively advanced technological capability where most poor people happen to live, for instance in Pakistan, India or China, may well differ from those in other countries such as many countries in sub-Saharan Africa with a weak capability. The impact of IP policies on poor people will also vary according to socio-economic circumstances.

The ability of IPR owners to charge above marginal cost derives from the exclusivity/'monopoly' which they are granted. Not necessarily a monopoly in an antitrust sense, it does limit competition to some degree. The effect on competition depends on the *nature* and *extent* of IPRs granted and the extent to which close substitutes are, or are likely to be, available. For example, patent rights provide *exclusive rights* over ideas, whereas copyright only provides protection against *copying* particular *expressions* of ideas; copyright does not provide protection against independent creation of an identical expression, or different expression of the same ideas. In this regard, patents are likely to have a much greater impact on competition than copyright.

Scope of Intellectual Property Rights

All countries need to determine and design IP policies and rules appropriate to their needs and level of development for crop biosecurity. IP is a means, not an end in itself. The one-size-fits-all approach is widely rejected, yet efforts continue by some transnational corporations and developed countries to have one set of global rules enforced by a global system. The question of IPRs and plant genetic material has thus become linked to "farmers' rights" in the case of the FAO undertaking, and, in the case of the Biodiversity Convention, to the "equitable sharing of the benefits arising from the utilization of plant genetic resources". Despite the undertaking by the signatories of the TRIPs agreement to introduce IPRs in one form or another to cover plant genetic material, plant varieties and plant parts, opinions differ widely over the possession and control of genetic resources and the role played by IPR regimes.

Protecting Bio-Assets: An Emerging Challenges to Crop Biosecurity

Worldwide attempts to preserve biodiversity and the information and materials generated by the genomics revolution present a significant new challenge to governments and industry. What biological resources should be preserved? Where should they be preserved? Who should be responsible for their preservation? How can governments co-operate to enhance efficiency? How can *ex situ* collections of plant genetic resources cope with the wealth of biodiversity and the vast quantity of information and products emerging from the genomics revolution?

Conservation of Diversity for Crop Biosecurity

During the 1970s and 1980s, developing nations expressed concern about the free flow of plant genetic resource materials or germplasm, from the South to the North. Why, they asked, were patented seeds of southern origin bringing tremendous profits to multinational seed companies without compensation for the developing world? In the culmination of what was dubbed as the *Seed Wars of the Eighties*, Third World leaders managed to air their concerns in an international arena via the FAO. In 1983, FAO established the Global System for the Conservation and Utilization of Plant Genetic Resources that includes a legally non-binding set of guidelines called the "International 'Undertaking' on Plant Genetic Resources" and an intergovernmental Commission on Plant Genetic Resources. The Commission monitors the implementation of the Undertaking and more generally discusses the use, control and conservation of plant genetic resources. It operates on the principle of one country, one vote. The purpose of the 'Undertaking' is to "ensure that plant genetic resources of economic or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and for scientific purposes." The underlying notion is the common heritage principle - that "plant genetic resources are a heritage of mankind and consequently should be available without restriction." The principle is extended to include not only native plant materials, but also farmer-developed varieties and new products of biotechnology.[11] This guarantee of access without restriction caused eight industrialized countries to register reservations; the U.S. and Canada still do not adhere to the 'Undertaking'.

Challenges of Crop Biosecurity to the Developing Countries

The South Asian region is one of the largest gene-rich regions of the world and equally rich in traditional and indigenous knowledge. The rich socio-cultural heritage of the developing countries is evident in that the plant variety has always remained freely accessible to all since times immemorial.[12]

Forthcoming legislations concerning the conservation of crop biosecurity should encompass the following points:

— Regulate crop biosecurity with reference to access of the biological resources of the country for purposes of securing an equitable share in benefits arising out of the use of biological, and associated knowledge relating to bioresources.
— Conserve and sustain use of biological diversity.
— Respect and protect knowledge of local communities related to biodiversity.
— Secure sharing of benefits with local people as conservers of biological resources and holders of traditional knowledge and information.
— Conserve and develop areas from the stand point of rich bioresources.
— Protect and rehabilitate endangered fauna and flora.
— Ensure active participation of the private sector, NGOs and local people in the broad sense of schemes for policy implementation for crop biosecurity.

The proposed legal reforms on the subject of crop biosecurity should address issues concerning access to genetic resources associated with knowledge by foreign individuals, institutions and equitable sharing of benefits arising out of these resources and knowledge between the host countries and the local people.[13]

In this connection exemptions should be made in the case of the following:

— Free access to biological resources for intra-country uses by country's own nationals other than commercial uses.
— Free access by country's own citizens to use bio-resources within the country for research purposes.
— Ensure the plant biosecurity and protection of the farmers' right to save, use, exchange or share the farm produce of a protected variety of crop without any limitation.
— Recognize the contribution of the farming community for the development of a new crop variety with due consideration to financial compensation following the commercial use of the new variety.
— Total ban on 'terminator technologies' that force the farmers to buy seeds every time they sow the crop.
— Use diversified genetic materials. To obtain more high yielding varieties concerning the legal access to bioresources capital would without doubt provide a safeguard to the interests of the local people.

The aforesaid suggestions depend for implementation upon CBD and TRIPs allowing developing countries to execute their international obligation in their own way without undermining the basic objectives of the multilateral agreements. As is evident, there are two schools of thought regarding the protection of biodiversity for crop biosecurity and traditional knowledge. One school recognizes the TRIPs paradigm whereas the other does not recognize the informal innovation of the community since communities are entitled only to compensation but not to the right to share the results. This approach speeds up the depletion of biodiversity within the control of indigenous and local communities and therefore would work against the objectives of the convention. This Western bias of the CBD assures to the Western countries the unhindered flow of raw materials for their biotechnology industry.[14]

So, the following facts drawn from the theme are:-

1. The CBD recognizes biotechnology as a necessary element for biodiversity conservation while totally ignoring dangers of biotechnology to the conservation of biodiversity and biosecurity.
2. CBD provisions on access and transfer of technology apply only to future transactions and it is inadvertently silent on the access to genetic resources in the gene banks of the Northern countries.
3. The provisions that contain the pro-South approach are subject to wide ranging qualifications including patent and other instruments in the IPRs regime.
4. CBD by recognizing patents, in fact, recognizes the TRIPs paradigm of patent rights, which is detrimental to the biodiversity conservation. This regime also denies the equitable sharing of the benefits.

Developing countries, however, can check the adverse implications on crop biosecurity by using certain provisions like *Articles 6, 8* and *10* etc., which provide a mandate to chalk out strategies to protect their biodiversity. The reasoning is simple; because Third World interest cannot be protected through the Western notion of conservation and biosecurity. Any attempt at conservation and sustainable use of biodiversity would not succeed without changing the development model. The existing production pattern encourages monoculture, homogeneity, over-production and over-exploitation of nature. Therefore, the success of biodiversity conservation with the present development model is bound to be a futile exercise.[15]

According to the bio-rich developing countries, the desirable scenario should be one in which their bio-assets are not exported without rewards by third parties. To achieve this objective there are some possible strategies and modalities to be followed by the enactment of appropriate biosecurity protection and legislation. To achieve this end in the developing countries, domestic conditions and traditional practices, peculiar to each country, should be carefully considered before adopting any biological diverse or crop biosecurity law under the international obligations.[16] If this is so, then the economy passages from the North in exchange of bioresources would be a dominating factor for the economic development and anti-poverty programmes of the South Asian countries. The region of maximum genetic diversity for a species represents its centre of origin.[17]

Some of the reservations of the countries in the South concerning genetic biodiversity are as follows.

— The Northern countries are gene poor while those in the South are gene rich (see Table 1). The North is technology rich while the South is technology poor. The Green Revolution and current biotechnology research has widened this gap.

— The importation of advanced breeding lines from the North into the South has replaced traditional landraces but contributes to a greater yield in the short run if supplied with enough inputs that causes unstable and/ or lower yield in the long run.

Table 1: Centre of Origin of Crops

S. No.	Center of origin	Crops
1	Southwest Asia (Fertile Crescent)	Cereals, legumes (peas, lentils, barley) and diploid cotton
2	Africa	Barley, emmer, flax, chickpea, pea, lentil, lettuce, onion, fig, grape, olive, millets, sorghum, African rice, yams, Coffee
3	China and Southeast Asia	Millet, vegetables, soybeans, rice, citrus, tea, bananas, mangos, coconut, sugar cane
4	America (Mexico, South America)	Maize, potato, sweet potato,bean, tomato, chili pepper, peanut, bottle gourds, cucurbits, sunflower, cotton, sweet potato, pineapple, papaya, avocado, tobacco, cassava (manioc), cacao (source of chocolate), vanilla, cashew, pecan, Brazilnut, ornamental flowers (*Zinnia*, marigold, *Fuchsia, Canna, Nicotiana, Salvia*), coca

Source: World Atlas of Biodiversity, UNEP World Conservation Monitoring Centre, USA , 2002.

- The value of genetic resources in agricultural improvement in developing countries is misunderstood and underrated. Farmers have identified and classified valuable genetic material in landraces (often according to indigenous taxonomic systems), and selected, bred, and named them.
- Farmers in developing countries are not rewarded for their contribution to the North's agricultural production since landraces are believed to be freely available. The patent system in the North leaves no room for reward for landraces.
- The North controls not only the use of genetic resources, but also their collection and exchange. It favours centralized gene bank systems which limits the South's access to them.
- Genetic resources in the IARC, CGIAR Centres and most Western gene banks are freely available with the South benefiting from the knowledge resource base.
- The agro industry is mostly dominated by the North that protects its products through property rights even though the basic material for these products usually originates from the South.

North America (US and Canada), Australia, the Mediterranean, Africa, and Europe/Russia are more than 85 per cent dependent upon foods originating outside their region Crops in these regions are dependent upon the centres of diversity for germplasm for genetic improvement of their crops.

High Price, Patents and PVPs

The world's poorest nations as a group account for 96 per cent of the world's genetic resources "It is partly the uneven distribution of genetic resources and global food production that has led to international debate over the control of genetic resources. The fact that the so-called 'gene-poor' countries have been able to dominate the world food production underscores the limitations in reducing agricultural production to the global distribution of genetic resources. In addition to these resources, success in agricultural production depends largely on the technological and scientific capability to enhance production using the available genetic resources. It is, therefore, no surprise that the industrialized countries, despite being 'gene-poor', have been able to dominate the world in agricultural production. The debate on the control of genetic resources is meaningful only if conducted in the context of broader policies and strategies for scientific and technological development.[18]

Agricultural biodiversity is the result of the careful selection and inventive developments of farmers, herders and fishers over millennia. Agricultural biodiversity is a vital sub-set of biodiversity. It is a creation of humankind whose food and livelihood security depend on the sustained management of those diverse biological resources that are important for food and crop biosecurity. Agricultural biodiversity results from the interaction between the environment, genetic resources and the management systems and practices used by culturally diverse peoples resulting in the different ways that land and water resources are used for production. It thus encompasses the variety and variability of animals, plants and micro-organisms which are necessary to sustain key functions of the agro-ecosystem, its structure and processes for, and in support of, food production and food security.

Biodiversity is undoubtedly the foundation from which biotechnology develops and upon which the industry is strongly anchored. Likewise, biotechnology has much to offer to the conservation of a sustainable use of biodiversity for the survival of species in restoring or enhancing the resilience of ecosystems.

The fact that rich nations are home to the smallest pockets of biodiversity while the poor are stewards of the richest resources underlines the interdependency of all nations in addressing the urgency of formulating common biosecurity strategies for sustaining biodiversity as well as for the sharing of responsibility and benefits.

Genetic Erosion

Genetic erosion is the loss of genetic diversity, including the loss of individual genes, and the loss of particular combinations of genes (i.e. of gene-complexes) such as those manifested in locally adapted landraces. The term "genetic erosion" is sometimes used in a narrow sense, i.e. the loss of genes or alleles, as well as more broadly, referring to the loss of varieties. The main cause of genetic erosion in crops, as reported by almost all countries, is the replacement of local varieties by improved or exotic varieties and species. As old varieties in farmers' fields are replaced by newer ones, genetic erosion frequently occurs because the genes and gene complexes found in the diverse farmers' varieties are not contained *in toto* in the modern variety.[19] In addition, the sheer number of varieties is often reduced when commercial varieties are introduced into traditional farming systems. While some indicators of genetic erosion have been developed, there have been few systematic studies of the genetic erosion of crop genetic diversity which have provided quantifiable estimates of the actual rates of genotypic or allelic extinction. Nearly all countries say, in Country Reports to FAO for the Leipzig Conference in 1996, that genetic erosion is taking place and that it is a serious problem (see Table 2).

The genetic erosion of agricultural biodiversity is also exacerbated by the loss of forest cover, coastal wetlands and other 'wild' uncultivated areas, and the destruction of the aquatic environment. This leads to losses of 'wild' relatives, important for the development of biodiversity, and losses of 'wild' foods essential for food provision, particularly in times of crisis. Variety replacement is the main cause of losses. The replacement of local varieties or landraces by improved and/or exotic varieties and species is reported to be the major cause of genetic erosion around the world. It is also cited as the major cause of genetic erosion in all regions except Africa. Examples are mentioned in 81 Country Reports, of which a number are highlighted below. As survey of farm households in the Republic of Korea showed that of 14 crops cultivated in home gardens, an average of only 26 per cent of the landraces cultivated there in 1985 were still present in 1993. The retention rate did not exceed 50 per cent for any crop, and for two crops it was zero. These results are disturbing as such home gardens have traditionally been important conservation sites, especially for vegetable crops. In China, in 1949, nearly 10,000 wheat varieties were used in production. By the 1970s, only about 1,000 varieties remained in use. Statistics from the 1950s show that local varieties accounted for 81 per cent of production, locally produced improved varieties made up 15 per cent and introduced varieties 4 per cent. By the 1970's, these figures had changed drastically; locally produced improved varieties accounted for 91 per cent of production, introduced varieties 4 per cent and local varieties only 5 per cent.

Biopiracy: A Threat to Crop Biosecurity

There is no accepted definition of "biopiracy." The Action Group on Erosion, Technology and Concentration (ETC Group) defines it as "the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control (usually patents or plant breeders' rights) over these resources and knowledge".[20]

Table 2: Hotspots of Different Plants in the World at a Glance

Area	Original hotspot area (sq km)	Hotspot area today (sq km)	Protected area (sq km)	Total plant species	Total terrestrial vertebrate species	Terrestrial vertebrates under threat*	Extinct Species Since 1500
Atlantic Forest	1,477,500	121,600	33,000	20,000	1,668	116	1
Brazilian Cerrado	1,783,200	356,630	92,729	10,000	1,268	22	0
California Floristic Province	324,000	80,000	31,443	4,426	584	12	0
Cape Floristic Region	74,000	18,000	14,060	8,200	562	15	2
Caribbean	263,500	29,840	41,000	12,000	1,518	99	51
Caucasus	500,000	50,000	14,050	6300	632	10	0
Central Chile	300,000	90,000	9,167	3,429	335	8	0
Chocó-Darién-Western Ecuador	260,600	63,000	16,471	9,000	1,625	32	0
Eastern Arc Mountains and Coastal Forests	30,000	2,000	5,800	4,000	1,109	43	1
Guinean forests of West Africa	1,265,000	126,500	20,324	9,000	1,320	70	0
Indo-Burma	2,060,000	100,000	100,000	13,500	2,185	106	1
Madagascar and Indian Ocean Islands	594,150	59,038	11,548	12,000	987	123	46
Mediterranean Basin	2,362,000	110,000	42,123	25,000	770	42	4
Mesoamerica	1,155,000	231,000	138,437	24,000	2,859	62	4
Mountains of Southwest China	800,000	64,000	16,562	12,000	1,141	34	0

Area	Original hotspot area (sq km)	Hotspot area today (sq km)	Protected area (sq km)	Total plant Species	Total terrestrial vertebrate species	Terrestrial vertebrates under threat*	Extinct Species Since 1500
New Caledonia	18,600	5,200	526.7	3,332	190	9	1
New Zealand	270,500	59,400	52,068	2,300	217	61	25
Philippines	300,800	21,000	25,995	7,620	1,114	103	0
Polynesia and Micronesia	46,000	10,024	4,913	6,557	342	88	38
Southwest Australia	309,850	33,336	33,336	5,469	456	25	5
Succulent Karoo	116,000	30,000	2,352	4,849	472	12	0
Sundaland	1,600,000	125,000	90,000	25,000	1,800	82	0
Tropical Andes	1,258,000	314,500	79,687	45,000	3,389	130	2
Wallacea	347,000	52,020	20,415	10,000	1,142	82	0
Western Ghats and Sri Lanka	182,500	12,450	12,450	4,780	1,073	31	0

Source: Conservation International Endemic species of terrestrial vertebrate, Biodiversity Hotspots/Conservation International (www.biodiversityhotspots.org)

The following have been described as "biopiracy":

(a) ***Granting of 'wrong' patents*** for inventions that are neither novel nor inventive having regard to traditional knowledge already in the public domain. Such patents may have been granted due either to oversights during patent examination or simply because the patent examiner did not have access to the knowledge.[21] This anomaly may be because the knowledge is written down but not accessible using the tools available to the examiner, or because it is unwritten knowledge. A WIPO initiative to document and classify traditional knowledge seeks to address some of these problems was made in 2001.

(b) ***Granting of 'right'*** *patents* in accordance with national law on inventions derived from a community's traditional knowledge or genetic resources. This "biopiracy" results since:

Patenting standards are too low for inventions that amount to little more than discoveries. Alternatively, the national patent regime (for example, in the US) may not recognize some forms of public disclosure of traditional knowledge as prior art. Even if the patent represents a genuine invention, however defined, no arrangements may have been made to obtain the prior informed consent (PIC) of the communities providing the knowledge or resource, and for sharing the benefits of commercialization to reward them appropriately in accordance with the principles of the CBD.

Controversial Patent Cases involving Traditional Knowledge and Genetic Resources

Some cases of biopiracy relating to patents of agricultural crops are listed below to illustrate the issues faced by current IPR regulations.

Rice

The "Battle for Basmati", an aromatic variety of rice, started in 1997 when US Rice breeding firm RiceTec Inc. was awarded a patent (US5663484) relating to plants and seeds, seeking a monopoly over various rice lines including some having characteristics similar to Basmati lines. Concerned about the potential effect on exports, India requested a re-examination of this patent in 2000. The patentee in response to this request withdrew a number of claims including those covering basmati type lines. Further claims were also withdrawn following concerns raised by the USPTO. The dispute has however moved on from the patent to the misuse of the name "Basmati."

Turmeric

Turmeric (*Curcuma longa*) a plant of the ginger family yielding saffron coloured rhizomes used as a spice for flavouring in cooking has properties that make it an effective ingredient in medicines, cosmetics and as a colour dye. As a traditional medicine it is used to heal wounds and rashes. In 1995, two Indian nationals at the University of Mississippi Medical Centre were granted US patent no. 5,401,504 on "use of turmeric in wound healing". The Indian Council of Scientific and Industrial Research (CSIR) requested the US Patent and Trademark Office (USPTO) to re-examine the patent. CSIR argued that turmeric has been used for thousands of years for healing wounds and rashes and its medicinal use was not novel as per documentary evidence of traditional knowledge, including an ancient Sanskrit text and a paper published in 1953 in the *Journal of the Indian Medical Association*. Despite arguments by the patentees, the USPTO upheld the CSIR objections and revoked the patent.

Observations: The turmeric case was a landmark case as it was the first time that a patent based on the traditional knowledge of a developing country had been successfully challenged.

Neem

Neem (*Azadirachta indica*) is a tree from South and Southeast Asia now planted across the tropics because of its properties as a natural medicine, pesticide and fertilizer. Neem extracts can be used against hundreds of pests and fungal diseases that attack food crops. Oil extract from its seeds is used to treat colds and influenza; and when used in soap, seemingly, offers low cost relief from malaria, skin diseases and even meningitis. In 1994, the EPO granted European Patent No. 0436257 to the US Corporation W.R. Grace and USDA for a "method for controlling fungi on plants by the aid of hydrophobic extracted neem oil". In 1995, a group of international NGOs and representatives of Indian farmers filed a legal opposition against the patent with evidence that the fungicidal effect of extracts of neem seeds had been known and used for centuries in South Asian agriculture to protect crops thus indicating the invention claimed in EP257 was not novel. In 1999, the EPO determined that according to the evidence "all features of the present claim have been disclosed to the public prior to the patent application… and [the patent] was considered not to involve an inventive step". The patent was revoked by the EPO in 2000.

Ayahuasca

For generations, shamans of indigenous tribes throughout the Amazon Basin have processed the bark of *Banisteriopsis caapi* to produce a ceremonial drink called "ayahuasca". The shamans use ayahuasca or "vine of the soul" in religious and healing ceremonies to diagnose and treat illnesses, meet with spirits, and divine the future. A US national Loren Miller obtained US Plant Patent 5,751 in June 1986, granting him rights over an alleged variety of *B. caapi* he had called "Da Vine". The patent description stated that the "plant was discovered growing in a domestic garden in the Amazon rain-forest of South America." The patentee claimed that Da Vine represented a new and distinct variety of *B. caapi*, primarily because of the flower colour. The Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA) – an umbrella organization representing over 400 indigenous groups – learned of the patent in 1994. On their behalf the Centre for International Environmental Law (CIEL) filed a re-examination request on the patent. CIEL protested that a review of the prior art revealed that Da Vine was neither new nor distinct and argued that the granting of the patent would be contrary to the public and morality aspects of the Patent Act because of the sacred nature of *Banisteriopsis caapi* throughout the Amazon region. Extensive, new prior art was presented by CIEL, and in November 1999, the USPTO rejected the patent claim agreeing that Da Vine was not distinguishable from the prior art presented by CIEL and therefore the patent should never have been issued. However, further arguments by the patentee persuaded the USPTO to reverse its decision and announce in early 2001 that the patent should stand.

Observation: Because of the date of filing of the patent, it was not covered by the new rules in the US on *inter partes* re-examination. CIEL were therefore unable to comment on the arguments made by the patentee that led to the patent being upheld.

Hoodia Cactus

The San, who live around the Kalahari Desert in southern Africa, have traditionally eaten the *Hoodia* cactus to stave off hunger and thirst on long hunting trips. In 1937, a Dutch anthropologist studying the San noted this use of *Hoodia*. Scientists at the South African CSIR only recently found his report and began studying the plant. In 1995, CSIR patented *Hoodia*'s appetite-suppressing element (P57) and in 1997 licensed P57 to the UK biotech company Phytopharm. In 1998, the pharmaceutical company Pfizer acquired the rights to develop and market P57 as a potential slimming drug and cure for obesity (with a market worth more than £6 billion) from Phytopharm for up to $32 million in royalty and milestone payments. On hearing of possible exploitation of their traditional knowledge, the San people threatened legal action against the CSIR on grounds of "biopiracy" and claimed that their traditional knowledge had been stolen, and that the CSIR had failed to comply with the rules of the CBD which requires the prior informed consent of all stakeholders, including the original discoverers and users. Phytopharm had conducted extensive enquiries but were unable to find any of the "knowledge holders". The remaining San were apparently at the time living in a tented camp 1500 miles from their tribal lands. The CSIR claimed they had planned to inform the San of the research and share the benefits, but first wanted to make sure the drug proved successful. In March 2002, an understanding was reached between the CSIR and the San whereby the San, recognized as the custodians of traditional knowledge associated with the *Hoodia* plant, will receive a share of any future royalties. Although the San are likely to receive only a very small percentage of eventual sales, the potential size of the market means that the sum involved could still be substantial. The drug is unlikely to reach the market before 2006, and may yet fail as it progresses through clinical trials.

Observations: This case would appear to demonstrate that with goodwill on all sides, mutually acceptable arrangements for access and benefit sharing can be agreed to. The importance of intellectual property in securing future benefits appears to have been recognized by all parties including the San.

Raising of Voice against Biopiracy

The issue of biopiracy mostly raised by under-developed biodiversity-rich countries (e.g. Pakistan, India, Brazil, and Malaysia, among others) and by some NGOs (e.g., GRAIN, ETC (previously RAFI) and the Third World Network) is not always acknowledged by corporations and governments. According to some, biopiracy is not only happening at the expense of Third World farmers but also occurs at the expense of Northern farmers. Some American and European farmers consider themselves to be compelled with contracts limiting their independence. Some companies argue that they are losing millions of dollars per year because of lack of respect of patents and that under-developed countries are themselves guilty of piracy believing that the Southern countries do not have adequate and efficient intellectual property protection laws. These companies have been applying pressure for the strengthening of IP issues within the WTO. Companies say access to biological resources allows them to develop new products that could help solve food and health essential issues and argue that research, development and commercialization authorizations have a cost that must be balanced by the protection of the resulting product. Patents offer this much needed revenue and favour innovation.

One of the solutions suggested to solve this North-South disagreement was to instutute bilateral bioprospecting contracts between source-country and pharmaceutical or seed companies which define and lay down the rules of benefit sharing, and that can potentially bring substantial royalties to Southern countries. Such agreements can result in high potential benefits for the source-country. However, there are several reasons why this usually does not happen since bilateral contracts are not always respected as they do not propose a fair trade. By admitting that the principle of compensation of the populations is retained, there remains the issues of which and what amount could be an equitable and realistic remuneration? How could the rights be redistributed? Other considerations are:

— Lack of awareness of the potential value of the products.
— Very few of the samples collected actually lead to a new profitable product.
— Lost ownership in the case of genetic modification.
— Majority of concerned species to be found in several countries at the same time, thus preventing some of them from taking advantage of the product, or diluting the benefits for all.
— Protection of collective knowledge doesn't fit within the legal systems of IPR protection (e.g. patents, copyrights, trademarks)

Options considered by Southern countries include:

— Documentation of traditional knowledge.
— Registration and innovation system.
— Easier and less expensible patenting system.
— Development of a *sui generis* system.
— Development of own research.
— Creation of alliances of source-countries.

The implications for the source-country are as follows:

- Possible necessity for the farmers to use the new patented variety, implying increasing dependence on the company owning the seed, especially in case of monopoly.
- Prohibition of the use of the seed for any further breeding;
- Increased dependence on developed countries for the product
- Loss of biodiversity resulting from increased monoculture, monospecies culture and lack of access to seed stocks.
- Possible financial loss when fair agreement on benefit sharing between the source country and the company was not achieved.
- Possible loss of traditional community knowledge, with limited to nil compensation.

The concept of biopiracy assumes that it is a natural right to own plants, animals and human genes. Some do not follow this principle and consider that users from all over the world need to be free to manufacture drugs, free to cultivate and to raise plants and animals. For many indigenous people, nature and culture are indissociable. Resources belong to the community, private property has no meaning. They argue that what is "wrong" is not so much the appropriation of somebody else's property, but rather to consider as private, natural resources that should stay public.

It is important to understand that authors and inventors exercise specific rights, and the "property" referred to in "intellectual property" is the rights, and *not* the intellectual work. A patent can be bought and sold, but the invention that it covers is not owned at all. This is one of many reasons that some believe the term *intellectual property* to be misleading. Some use the term "intellectual monopoly" instead, because such so-called "intellectual property" is actually a government-granted monopoly on certain types of action. Others object to this usage, because this still encourages a natural rights notion rather than a recognition that the rights are purely statutory, and it only characterizes the "property" rather than eliminates the property presupposition. Others object to the negative connotation of the term "monopoly" and cite the wide availability of substitute goods. Still others prefer not to use a generic term, because of differences in the nature of copyright, patent and trademark law, and try to be specific about which they are talking about, or the term "exclusive rights", which reflects the U.S. Constitutional language.

Plant genetic resources are essential to a sustainable agriculture and biosecurity. FAO estimates humans have used some 10 000 species

Table 3: Plant Species Used as Food by Humans

Human use/classification	Plant species
Total described species	250,000
Edible	30,000
Cultivated	7,000
Important on national scale	120
Making up 90 per cent of world's calories	30

Source: UN Food and Agriculture Organization, 1997) FAO. *State of the World's Plant Genetic Resources for Food and Agriculture* (*www.fao.org/WAICENT/FaoInfo/Agricult/AGP/AGPS/pgrfa/pdf/swrfull.pdf*)

for food throughout history. However, only about 120 cultivated species provide around 90 per cent of food requirements and 4 species (maize, wheat, rice and potatoes) provide about 60 per cent of human dietary energy for the world's population (see Table 3). Of the myriad of varieties of these crops developed by farmers over millennia, which form an important part of agricultural biodiversity, more than 75 per cent have been lost in the past 100 years. Many hope this new and much needed Treaty will make a difference.

In view of the rapid advances in transport and trade, awareness of biological diversity/environmental issues and technological progress, improved national and international frameworks and standards are required to regulate, manage and control biosecurity of food and agriculture (including forestry and fisheries). Biosecurity has direct relevance to food safety, conservation of the environment (including biodiversity), and sustainability of agriculture. As biosecurity is increasingly based on the management of risk, there is a growing need for a risk assessment framework to be established at the national level that helps define and rank the values of all sectors being protected. Such a framework should also help manage tensions, for example, between pre-border and border measures designed to manage biosecurity risks associated with trade and travel, and post-border measures aimed to detect and manage risks associated with harmful new organisms or established hazards (pests).

Threat of Bioterrorism to Agricultural Crop Biosecurity

An agro-terrorism attack could result in any of the two forms namely, agricultural biowarfare and bioterrorism.[22] Undue agri-technology protection leading to adverse affects on the food security of a country should also be considered as a form of agricultural biowarfare. This may cause a loss to crop biosecurity in the following ways:

— Reduced production of food (although unlikely to be an issue in a rich country, starvation could occur in poor countries with limited resources).
— Dramatic economic loss within the affected agricultural sector or sectors (through direct loss of crops or animals, cost of containment activities, or reduced domestic demand).
— Export embargoes that would remove agricultural products from the global market.
— Destabilization of related economic markets (such as revenue losses to shippers, processors, exporters, and others).
— Creation of social instability causing the local population to lose confidence in the safety of the food supply and by inciting fear and a sense of vulnerability.

A bioterrorist attack on agricultural targets has been considered by some to be a "high consequence–high probability event"[23] for the following reasons**:**

— The technological barriers to obtaining and weaponizing agricultural pathogens are relatively minimal.
— Many crop and animal pathogens can be isolated from the environment or obtained from laboratories without substantial difficulty.
— An attack against crops or livestock could be carried out relatively easily without sophisticated equipment or expertise.
— Only a small quantity of the affecting agent would be needed since many of the agents of concern are highly transmissible between animals or, for plant diseases, via the air.
— Crops are openly exposed and relatively vulnerable to an attack.
— Livestock and poultry often are raised under conditions involving high concentrations of animals

Certain sectors of the food-production industry are geographically localized. An attack on one sector could have a dramatic impact on a local, state, or regional economy. Limited genetic diversity in agriculture promotes susceptibility to specific pathogens. Damaging crops and livestock is not as morally serious as committing terrorist acts involving loss of human life. Hence, agroterrorism may be more acceptable to some potential perpetrators of biocriminal intent than other forms of terrorism.[24]

In addition to a direct impact on producers, an attack on a sector of agriculture would have a ripple effect on other industries. For example, an attack would affect shippers, wholesalers, distributors, exporters, retailers, and possibly other aspects of the economy, such as tourism.[25] The states most vulnerable to economic attack on the agricultural sector are those with several or most of the following attributes:

— High-density, large area agriculture.
— Heavy reliance on monoculture of a restricted range of genotypes.
— Free of specific serious animal and plant pathogens or pests.
— Major agricultural exporter, or heavily dependent on a few domestic agricultural products.
— Suffering serious domestic unrest, or the target of international terrorism, or unfriendly neighbor of states likely to be developing biological warfare (BW) programs.
— Weak plant and animal epidemiological infrastructure.

For such at-risk states, the threat of biological attack against their agricultural sectors should be taken quite seriously, and preventive and punitive measures be put in place.

Enactment of legislation implementing the Biological and Toxins Weapons Convention (BTWC) is required of all states parties; however, many have not yet done so. Such legislation can be a significant deterrent to biological attack on the agricultural sector. The legislation should, among other provisions, provide for substantial criminal penalties for the hostile use anywhere of biological agents against plants or animals as well as people, and it should provide for extradition for anyone charged with using such agents against the agricultural sector of another state. States that already have enacted such legislation should review its provisions to ensure that they adequately cover biological attack on plants and animals.

A biological attack on the agricultural sector is likely to be covert. Such attacks will be options for perpetrators only to the extent that they are able to maintain the plausibility that such events are natural events. Increased epidemiological capacity, especially in strain identification from molecular sequence data, makes it increasingly difficult to escape detection, and thus would act as a substantial deterrent.[26]

A BTWC Protocol that establishes effective measures to deter States from developing or possessing biological weapons would provide a powerful tool in making progress towards the goal of complete biological disarmament. This would reduce the likelihood of BW in regional conflicts, and the chance that state-supported terrorist organizations would ever get bioweapons. Provision for internationally sponsored epidemiological investigation of possible agricultural attacks would deter covert use in the same manner as national epidemiological capacity.

States that engage in high intensity agriculture of a limited range of varieties could reduce their vulnerability to both deliberate and natural disease outbreaks by increasing the use of intercropping, expanding the diversity of genotypes utilized, reducing the size of plots, and a variety of other agricultural changes designed to reduce susceptibility to disease outbreaks. However, these constitute substantial changes in established practice, and are probably not likely to be instituted without sustained and forceful political leadership.

Future of IPRs and Biotechnology and Crop Biosecurity

There is little doubt that the breakthroughs in biotechnology, genomics and genetics will affect our societies and many aspects of human daily life as profoundly as the information technologies have already done. Biodiversity and genomics will be the source not only of tremendous amounts of biological materials, from large organisms to miniature genes but also a source of data that will be a key to R&D in the life sciences especially for crop biosecurity.

Biological materials and data have long been preserved in and disseminated by repositories of microbial culture collections, and seed banks. These biological collections face great challenges and great opportunities owing to the explosive increase in biological materials and data.[27]

Concern has been expressed particularly amongst NGOs that developing countries will be deprived of access to new genetic technologies directly when technology is protected by IPRs and indirectly when they are unable to pay the higher costs implied.

It should be recalled that "access" to genetic technologies concerns both end-products as well as inputs into the research process. Another aspect of the issue of accessibility is the concern of developing countries to retain control over the exploitation of indigenous genetic resources. In accordance with the terms of the CBD, developing countries may restrict access to these resources — for example, to companies of developed countries — unless they have first entered into a formal agreement on access (such as the Prior Informed Consent agreements) and that they are assured of a share in the benefits. To date, however, few countries such as India, and China have enacted national legislation to curtail access.[28]

In the past, diverse germplasm held in gene banks and bio-material resulting from their own research were made freely available to developed and developing countries as well as to public and private sector research institutes and firms. However, comparison of the costs and benefits of importing or purchasing genetic technologies versus local development are likely to be further complicated with the introduction of IPRs. One of the key issues at stake for developing countries is whether IPRs are likely to enhance the role of local innovators and, by implication, strengthen national innovation capability.

The evidence referred to earlier[29] suggests that private investment in research and plant breeding would be stimulated by the introduction of IPRs for those crops where commercial demand exists. For open-pollinated varieties and for the crops of resource-poor farmers it is unlikely that private companies will invest in R&D unless provided with incentives. It is also unlikely that IPRs alone would provide sufficient incentive to influence the behaviour of local innovators if other conditions such as a generally favourable environment for investment and for private sector development were not met with. Whilst it is true that in many developing countries, agricultural R&D remains concentrated in the public sector institutions given current difficulties in funding public research there is a growing awareness of the need to stimulate private sector involvement. In several countries, different types of incentives such as tax incentives, credit support, screening or testing services are being offered to private firms either to stimulate public/private sector collaboration in research, or to stimulate the creation of local firms for the development of new technologies[30] contributing towards crop biosecurity. One of the most effective ways of acquiring the hardware aspects of technology and the more "tacit" aspects is through different forms of collaboration or joint ventures with foreign companies. Even in the absence of IPRs related to plants many of the major seeds and agro-chemical companies, a number of multinational companies inclusive of those with major research programmes at the forefront in genetic technologies, have either set up subsidiaries or entered into joint ventures in developing companies.

Role of Public Sector in IPR

The public sector R&D is well developed in a number of developed countries. With structural adjustment and liberalization, public research institutions are under pressure to become involved in income-generating activities. Revenues from licensing or royalties, or from the provision of services, could therefore become important for those institutions, which, until now, have made their “innovations” freely available to both public and private sectors. The need for public sector research in agriculture will remain despite the private sector assuming a growing role in innovation. The introduction of a national IPR system may even facilitate a more rational public/private division of biosecurity roles. One of the important constraints in elucidating this biosecurity role is a very weak private sector R&D activity related to biotechnology and other crop biosecurity related issues in a majority of the developing countries.[31]

Most of the biotech research, at whatever level, is being undertaken in the public sector of the developing countries. For any public/private partnership, the private sector from the developed world has to be involved. This is all the more true in cases where cells, organelles, genes or molecular constructs are under patent with some of the big multinational biotech companies. In many cases, the material under patent has its origin from the germplasm or material located at some other place.[32] Moreover, based on legal interpretations of IPR laws, some advanced countries have been providing protection to biological processes and products which essentially do not fulfill the stringent application of the condition of novelty or discovery. Some such examples have already been stated above. Complications are also known to arise while making available any biotechnology product to the poor farming communities.[33]

Policy and Infrastructure Requirements for Crop Biosecurity

This paper indicates that policy and infrastructure requirements are needed to ensure that biotechnology will benefit the communities such as:

— Generate, adapt, and/or negotiate access to biotechnology innovations for crop biosecurity.
— Generate good quality animal and plant germplasm where biotechnology can be used.
— Generate capacity and capability to identify and prioritize critical problems affecting biosecurity concerning biotechnology.

— Development of a technology and information delivery system.
— Development of a science-based transparent biosecurity regulatory system.
— Capability of the public sector and the IARCs to negotiate, promote and deliver private-public partnerships in an environment where biotechnologies for crop biosecurity can be considered public goods.

Public and private sector research institutions need to emphasize biotechnology innovations that will express the following traits:

- Pest resistance that offers benefits to farmers in need of genetic control mechanisms where cultural practices are not effective and where a reduction in pesticides is advantageous leading to the need for more research to assess sustainability of resistance expressed in transgenic pest-protected plants
- Improved yield through isolation of dwarfing genes originally used to increase yields of cereals during the green revolution has now been shown to have the same effect with the potential to increase yield in other crops.
- Tolerance to biotic and abiotic stresses such as genetic control of the rice yellow mottle virus is one example of how transgenics can accomplish resistance when transgenics work to extend such benefits to smallholder farming communities
- Nutritional benefits such as increasing nutritional elements of many plant varieties such as transgenic research that enhances vitamin A content and elevated iron levels for developing countries.
- Reduced environmental impact: producing crops that tolerate stressful conditions, by introducing GM traits that control root diseases and that will help farmers cultivate crops where reduced tillage is essential. Conventional approaches failed to do so illustrating the need for public funded research.

Challenges of IPRs in Crop Biosecurity

- Countries should increase their efforts to achieve greater international harmonization of the laws, rules and practices governing access. Legal and regulatory differences among countries, particularly with regard to health and safety, use of plant materials and IPR can lead to unnecessary restriction of access to and exchange of plant genetic resource materials.

- Governments must remain alert to possible negative long-term consequences of restrictive gene licensing practices on crop biosecurity and plant biotechnology and on the rights of research institutions to provide access to genetic biological resources, and must be prepared to address these negative consequences when they can be documented.
- Governments need to work towards international harmonization of the broad variety of laws, regulations and practices aimed at protecting the health and safety of humans, animals, plants and the environment from potentially hazardous biological materials. This will discourage inappropriate uses of biological resources and will ensure crop biosecurity.
- Gvernments need to develop internationally compatible laws, standards and practices regarding plant materials and data, in order to protect crops, so that the unethical handling of biological materials and data from plants can be guaranteed.

Conclusion

Notwithstanding the term, 'biosecurity' which implies the sustenance of biogenetic resources, there is strong evidence of convergence, improved cooperation and integration of services and functions amongst the food safety, plant, animal, life, health and environmental sectors to achieve better regulation of biosecurity. Forces driving this change are increasing international agricultural trade and travel, biotechnological and information technology advances within a multicultural approach based on cross-cutting concepts for crop biosecurity.

Endnotes

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Note: * See also Additional reading (*www.fas.org/bwc/agr/reading.htm*) for several other documents relayed to this subject.