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THE TRADE-RELATED INTELLECTUAL PROPERTY AGREEMENT IN THE GATT 1994: IMPLICATIONS FOR AGRICULTURE AND THE ENVIRONMENT IN DEVELOPING COUNTRIES

by

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PURPOSE

For the first time, rules governing international trade, the General Agreement on Tariffs and Trade 1994 (GATT 1994), include an agreement on Trade-Related Intellectual Property (TRIP's). Amongst other things, the TRIP's agreement requires that Members of the World Trade Organization (WTO) upgrade their domestic legislation to allow for patenting of micro-organisms and plant and animals produced using non-biological and micro-biological processes. Plant varieties must be protected either by patents or by an effective *sui generis* system or any combination thereof (Art. 27(3)(b)). Patenting of plants and animals is optional. This paper examines the implications for developing countries of conforming to these new international rules.

The paper identifies the interests that are served by the new rules by exploring the technological developments that necessitated change, and the beneficiaries. An examination of the history of the negotiations gives a clear view of the competing interests of the North and South and the strategy used by the North to achieve its ends. The

specifics of the new regulatory framework are examined, and concerns about the effects on agriculture and the environment of these new arrangements, as expressed in the literature from a Southern perspective, are reviewed together with the views emanating from the North. The paper then examines suggestions for actions that could be taken by the South to protect its interests. Questions are posed on implications for Caribbean countries as a prelude to further work.

WHY THE CHANGES IN RULES?

Technological advances in genetic engineering in the industrialised countries have revolutionized the methods used to produce pharmaceutical products and varieties of plants with greater yields, tolerance to particular stresses, pests, and pathogens (Platais and Collinson 1992:34). This new method of production, biotechnology, involves "the manipulation of living organisms in order to alter their characteristics in some fashion, or to use them as a component of a broader

production process through a cluster of sophisticated bio-genetic techniques to alter cells or molecules directly" (Hingorani 1994:58). It was the discovery of DNA (1953) and the subsequent understanding of how it functioned, that is, the genetic code, that made it possible for scientists to identify and isolate economically important genes and transfer them into plants and animals, thus incorporating the desired characteristics (*ibid.*). For instance, seeds can now be produced incorporating natural resistance to certain pests or diseases, thus making redundant the related chemical or herbicides previously used to combat the problem. In 1995, approximately 20 transgenic crops of major importance were released for commercialization in several industrial countries, 14 of them in the USA alone (ISAAA 1996:1).¹

These technological inventions have led to the linking of R&D in genetic engineering at universities with venture capital supplied by multi-national corporations (MNC) in order to innovate (*Hingorani 1994: 58*). However, such ventures require heavy investment, and it takes 10-15 years before products are developed and released. Therefore, investors need to be certain of protection from unfair competition by having certainty of ownership and property rights in the invention. This would encourage investment in innovation by minimising the possibility of competitors unfairly using the invention for commercial purposes. This is particularly the case with respect to pharmaceutical and agro-biotechnology

industries (Platais and Collinson 1992:34). Research and development (R&D) in plant varieties has shifted from public sector institutions to the private sector, thus requiring a change in rules.

The need for protection of products of biotechnology was heightened by the ease with which the inventive step could be copied because it was embodied in the product. For instance, there is a growing trend whereby geneticists in some developing countries are extracting beneficial genes from a patented product, inserting them in a local variety, and patenting the improved variety. To combat this practice, current research seeks to imprint signatures on genes so that pirated genes can be traced (*ibid.*:63). There was therefore need to have protection available in all countries where the products of the invention could be sold.

However, intellectual property law is a matter for domestic legislation; a product patented in one country is not protected in another unless registered in the second country. The real problem is that the level of protection offered varied widely between the industrialized countries and developing countries and even between industrialized countries, though to a lesser extent. Existing intellectual property law (pre-TRIP's) in most developing countries would not give protection to products of biotechnology, pharmaceutical products or even plant varieties produced through hybridization methods. In many of these countries, intellectual property regimes were inherited from the colonial era and not upgraded since attaining independence. By contrast, regimes in the industrialized countries have been regularly upgraded to keep abreast of the new needs for protection arising out of technological developments in these countries.

¹ Approved transgenic crops now include maize, cotton and potatoes with insect resistance conferred by genes, herbicide resistant soybean and cotton; non-conventional virus-resistant squash and cantaloupes; delayed-ripening tomatoes; canola with modified oils and male sterility; and potatoes with modified starch as a quality trait (ISAAP 1996:1).

A minimum level of protection must therefore be available in the global market place so that MNC's could maximise market opportunities in the globalized world-economy under conditions that would secure the profits to themselves. This was necessary not only to safely sell products, but to safeguard investments in foreign countries by having the product or process patented in the host country. Basically, then, developing countries were required to upgrade their domestic intellectual property regimes to complement the technological advances in the North and the accompanying drive to market the derived products globally in order to maximise profits through full utilization of production capacity.

THE POLITICS OF THE NEGOTIATIONS

Prior to the inclusion of intellectual property protection in the GATT, the World Intellectual Property Organization (WIPO) administered international agreements and conventions on intellectual property rights (IPR), one of which was the *International Union for the Protection of Industrial Property/the Paris Convention* (1883) which included the patent system. It was recognized as far back as the 1950s that the patent system was having negative effects on the economies of developing countries (Penrose, 1951). The United Nations Department of Economic and Social Affairs conducted two studies, one in 1964 and an update in 1974 that confirmed these views. As a result, an Ad Hoc Group of Government Experts was established to steer the revision of the Paris Convention in an effort to reverse the unequal effects of the functioning of the industrial property regime. The Committee was required to take into consideration the role of patents in the

transfer and development of technology in developing countries (Rao, 1989).

The negotiations were protracted and divided along North/South lines. Eventually, there was deadlock. The North was disillusioned by the ineffectiveness of WIPO to achieve their objectives, particularly since it operated on a one country, one vote system which left the North in a minority. Moreover, WIPO had no enforcement powers. Northern countries succeeded in shifting the negotiations to the agenda for the Uruguay Round of GATT (Acharya 1991:73).

Southern countries were bitterly opposed to the inclusion of intellectual property in the agenda of the Uruguay Round and held this position until April 1989 when the leading countries, Brazil and India, changed their position under bilateral pressure from the United States. Both trade sanctions under the US Special 301 law and, in the case of India, a bilateral technological and scientific cooperation agreement were instrumental in achieving this change in position (Rao, 1989).

The US succeeded in enforcing a minimal level of harmonization of legislation and enforcement of holder's rights internationally through the TRIP's Agreement. It is interesting to note that everything that developing countries fought for in the negotiations on the revision of the Paris Convention from 1974 until 1989 was eventually given up in the negotiations of the TRIP's Agreement in the GATT. Table 1 below outlines the negotiating positions of South and North countries, and the eventual provisions in the TRIP's agreement in respect of pharmaceuticals, micro-organisms, and plants, animals.

All member countries of the WTO must comply with the requirements of the TRIP's Agreement. India was never a member of the Paris Convention and never offered intellectual property protection for products in pharmaceutical chemicals, only processed patents. This was a deliberate policy to encourage indigenous firms to invent alternative processes to produce cheaper versions of patented products as a means of making drugs available to a wider section of the society. This led to the mushrooming of an industrial sector producing cheap alternative supplies of drugs (generics). The same was the case in Brazil. In the TRIP's agreement, "protection of process" automatically applies to derived products and

vice versa. Both India and Brazil must now offer protection to pharmaceutical products. It is feared that this would lead to the demise of the indigenous pharmaceutical industry since it would discourage R&D in alternative processes. Developing countries did not offer IPP for plant varieties as a matter of public good, that is, to ensure food security and availability to as many as possible. Now they must offer IP protection of plant varieties either through patents or an effective *sui generis* system. There has been no definition of the term "effective", and it is assumed that this means the equivalent of the UPOV system which provides patent-like protection to plant breeders.

TABLE 1 Negotiating positions and Outcome in TRIP

Item	South Position	North Position	Outcome
Patentability of Pharmaceuticals	Should not be patentable. Allow accessibility to food and drugs - social good	Non-negotiable - leading edge in biotech + genetic engineering - pharm. increasingly relying on these methods.	Patentable and special protection in LDC's in period while law being developed
Patentability of biotechnology + genetically engineered products	Should not be allowed - contrary to traditional practices in LDC's/issues of ethics, bio-safety etc.	Need protection to encourage investment + secure profits. Must be patentable - US allowed patenting in 1985/ EU in 1991. Fierce competition for investment in new areas.	Art. 27(3)(b) Must Provide IP protection for cell + gene manipulations (frontier innovations) and fomentation processes (conventional methods)
Plant varieties	South countries did not belong to UPOV and did not want protection of plant varieties but wanted to maintain farmer's rights	UPOV created by North. Wanted minimum std. of Protection "effective protection."	Must provide for patents or effective, <i>sui generis</i> system = UPOV. Review in Jan. 1999 - lack of consensus
Patenting of plants + animals	Totally opposed	US favoured broad patent coverage	Optional "members may exclude from patentability plants and animals".

Source: Table compiled from information sourced from Rao and Dhar 1992.

TABLE 2 EVOLUTION OF PROTECTION UNDER THE UPOV SYSTEM

ITEM	1961	1978	1991
<ul style="list-style-type: none"> • Use of reproductive Material 	<ul style="list-style-type: none"> • Free to use Commercially 	<ul style="list-style-type: none"> • Pay royalty for commercial use 	<ul style="list-style-type: none"> • Pay royalty for commercial use
<ul style="list-style-type: none"> • Essentially derived Varieties Breeder's privilege - Research exemption 	<ul style="list-style-type: none"> • Free to breed and commercialize new variety 	<ul style="list-style-type: none"> • Free to breed and commercialize 	<ul style="list-style-type: none"> • Free to breed but cannot commercialize without permission from the owner of the initial protected variety (same under patent protection).
<ul style="list-style-type: none"> • Use of harvested Materials 	<ul style="list-style-type: none"> • Free use 	<ul style="list-style-type: none"> • Free use 	<ul style="list-style-type: none"> • Exclusive rights to breeder. - Pay royalty when selling unless royalty pd. on seeds - Pay royalty on products from harvested material unless royalty paid on seeds.
<ul style="list-style-type: none"> • Use of seeds 	<ul style="list-style-type: none"> • Permitted to use on-farm saved seeds for next product cycle Farmer's Privilege 	<ul style="list-style-type: none"> • Farmer's Privilege Remains 	<ul style="list-style-type: none"> • Farmer's Privilege remains only if a country passes legislation allowing farmers to use seeds for next crop within reasonable limits. Right holder can still claim that his "legitimate" interest is <u>prejudicated</u>.

Sources: Information drawn from Friends of Earth 1995; OECD 1996; Walden 1996.
Breeding of new varieties from protected varieties

THE ISSUE OF PROTECTION OF PLANT VARIETIES

There is a fundamental difference in the values underpinning the regime governing the use of new plant varieties in Western countries as opposed to non-Western countries. In the former, the rights and interests of individual and corporate persons are given primacy and therefore, protection. In the latter, the welfare of the community supercedes the rights of individuals. Production is organised largely around small farmers (some 85 percent of producers in developing countries). The practice in Southern countries has traditionally been to freely exchange resources through "over the fence" sale of seeds amongst farmers and barter-like exchanges (such as one bag of growing seeds for three bags of harvested grain and so on). Farmers, as a matter of course, saved seeds from their harvest for their next year's planting. This practice is known as "Farmer's Rights". (Friends of the Earth 1995: 16-18).

Based on the value of the primacy of community rights, the principle has always obtained that raw germ plasma had no owner, but was the "common heritage of mankind," freely available to all. Since the raw material was available freely, then it was considered fair exchange that access to the improved variety may also be free. This is important since improvement of varieties is not a static function, but an ongoing process that requires continuous access to new raw materials that are combined with farmer's existing improved varieties. **The source material is therefore a combination of wild genes plus farmer's varieties.**

In Western countries, a different set of rules evolved based on the primacy of individual rights. The discovery and use of the

hybridization process in the late 19th/early 20th centuries changed the method of seed procurement. Since seeds produced through hybridization were sterile, it became necessary to purchase new seeds for each planting, making seeds both the means of production and the product, and leading to its **commodification**. This process was intensified with the discovery and use of cross-hybridization that gave increased yields (Hingorani 1994: 56-57).

A change in the organization of production accompanied these technological developments in Western industrialized countries. Large-scale commercial agriculture controlled by MNC's displaced small farmers, particularly in the United States. These corporations invested in research and development (R&D) to develop plant varieties with greater yield capacity. The protection of rights over these new varieties in order to ensure that profits gained from their use accrue to the creators became an issue. It is in this context that the legal principles of Plant Breeders Rights emerged during the late nineteenth and first half of the 20th century. These were harmonized and formalized in 1961 under the *International Convention for the Protection of New Varieties of Plants* (known as the UPOV Convention). To obtain a plant breeders' right for a new variety (one not previously commercialized) it must be distinct from known varieties, uniform and stable (OECD 1996:19). To qualify for a patent, a variety must be novel, there must be an inventive step in its creation, it must be non-obvious and it must have industrial applicability, that is, it must be useful to society (utility).

Table 2 describes the evolution of protection granted under the UPOV system in its several revisions since 1961. One can clearly discern the growing trend towards the

granting of increasing monopoly rights and privileges and decreasing societal obligations to the right holder. This trend has culminated in the granting of patents to plant varieties.

Other changes in the 1991 revision are the extension of the scope of the Convention to all plant genera and species, and the provision for protection on the basis of "discovery" of a variety and a minimal level of subsequent development. The Convention also removes the previous obligation upon signatory nations not to grant both patent and plant breeder's rights to the same species (Walden 1996: 176-177).

Of grave concern to developing countries is the loss of Farmer's Privilege as an unquestioned right. Proactive legislation is needed to secure it, and challenges by the right holder are still possible. Until it became obvious in the TRIP's negotiations that developing countries would be forced to give protection to plant varieties equivalent to the UPOV system, no developing country chose to become a member. There was a rush, subsequently, to join UPOV 1978 before it was closed since UPOV 1991 had not as yet come into force, (because of non ratification by the minimum number of countries). Trinidad and Tobago was one such country that hastily passed its legislation for the protection of plant varieties and applied for membership of UPOV 1978. It was decided in April to keep UPOV 1978 convention open for another year to allow for the processing of pending applications. Future applicants must now join UPOV 1991, with its more stringent regulations.

Be that as it may, past experience suggests that it is only a matter of time before the North, led by the US, would enforce

international harmonization upward to UPOV 1991, or worse, make it mandatory to offer patent protection to plant varieties. Article 27(3) (b) of the TRIP's agreement comes up for review in January 1999 at the insistence of the US. This was because the US was unhappy with the fact that countries not obliged to make plant varieties, plants and animals patentable or at minimum, join the UPOV Convention were given the flexibility to develop an "effective" system of protection. No doubt, the evaluation would be based on an examination of "effectiveness" as measured by northern standards, and systems falling short of UPOV 1991 with which the North complies, may be deemed to be "ineffective".

According to Byrne (1991, quoted in Walden 1996: 176), the revision of UPOV in 1991 was designed to ensure the Convention's continued relevance as a form of legal protection in the face of the trend towards patenting of plant varieties. Given that the US now allows patenting of plant varieties (since 1985), it means that their plant breeders would be provided with lower protection elsewhere since if a variety is patented then Farmers Rights do not obtain. Possibly, the present partial securing of Farmer's Rights under UPOV 1991 may eventually be removed in subsequent revisions of UPOV under pressure from the US, or may be de facto removed through frequent exercise of the right to challenge by right holders. One has only to observe the trends in the development of intellectual property law in the US to discern that the evolution of protection required in international agreements is driven by the developments in US intellectual property law. Table 3 below illustrates this point.

TABLE 3 New Developments in US Intellectual Property Law which were included in the TRIP's 1994

Year	US Law
1980	US Supreme Court ruling that genetically-engineered microorganisms are patentable even though living organisms (Diamond v Chakrabarry) ^a
1985	Patenting of Plant varieties allowed ^b
1987	USPTO extended patent protection to non-naturally occurring non-human multi-cellular living organisms
1988	First transgenic animal patent issued to Harvard University of the Onco-mouse
1988	Patent Process Amendment Act - to link protection of process to product so as to prevent import of products manufactured through illegal use of process patent offshore.
1993	Biotechnology Patent Protection Act - permits biological process patents if <u>composition</u> of matter novel.

^a Patent upheld because DNA sequences are not normally found in the same organism. The decision recognized that a naturally occurring material may be prepared in a novel, non-natural form or used in a non-obvious way to render the material patentable.

^b UPOV 1991 allows the same specie to be protected both under Plant Breeders Rights and patent law.

COMMUNITY RIGHTS VERSUS INDIVIDUAL RIGHTS

The North/South contestation was taken to the UN Food and Agricultural Organisation (FAO) in 1989, in the negotiations for the revision of the 1983 FAO *International Undertaking on Plant Genetic Resources (Undertaking)*. In the 1983 Undertaking, Southern countries succeeded in widening the concept of "Common Heritage of Mankind" to encompass all plant genetic resources **including improved varieties** (Friends of the Earth 1995:9). The North totally disagreed with this broad interpretation of plant genetic materials. In 1989, the North insisted upon and succeeded

in passing an additional resolution that the *Undertaking* was not inconsistent with existing Plant Breeder's Rights (Lesser: 263).

Southern countries succeeded in re-defining the concept of Farmer's Rights as "rights arising from past, present and future contributions of farmers in conserving, improving and making available plant genetic resources" (Friends of the Earth 1995). This strikes at the heart of the concern of Southern countries, that farmers be compensated for their contribution to the creation and maintenance of the existing stock of plant varieties (in situ conservation) which are used to create new varieties. This should be done by a sharing of the financial

returns and through access to newly developed materials. Compensation was to be paid through the creation of an international fund for conservation and utilization of plant genetic resources (*ibid*).

There are several problems that make this apparent gain toothless. The *FAO Undertaking* is voluntary, not mandatory. Industrialised countries have reacted negatively towards it. No action has been taken to establish the International Fund. Moreover, Lesser (1994:263) strikes at the heart of the problem of differing value systems when he commented that Farmer's Rights operate more as a moral obligation than an economic incentive, with general conservation and [community] equity objectives. In view of this lack of support by the North for the *FAO Undertaking*, it is interesting to note the following statement in an OECD document on the issue of protection of genetic resources:

The Member Countries of the OECD and many other countries continue to recognise and honour the principle of unrestricted access to genetic resources (in accordance with the International Undertaking on Plant Genetic Resources for Food and Agriculture), while also accepting the need to reconcile this with the sovereign rights of States over their own resources, and the resulting authority to determine access to genetic resources, as recognised in the Convention on Biological Diversity. (OECD 1996:8).

What in fact is reflected in this statement, when posited against the 1989 Resolution that the Undertaking is not inconsistent with Plant Breeder's Rights, is that the North wants to maintain as far as possible free access to genetic resources in the wild, but be able to secure intellectual property

protection and therefore economic gains for products derived from these genetic resources.

There is a fundamental inconsistency in this position since the two principles are underpinned by opposite and conflicting value systems. There must be consistency one way or the other, and Southern countries should argue for internal coherence and consistency in the arguments adopted by the North, and not allow convenient use of principles to suit their purposes. Recognition by the North of "sovereign rights" under the Convention on Biological Diversity is safe and token, since it is up to the State to exercise that right, and many Southern countries have tremendous problems in doing so.

THE ISSUE OF ACCESS TO GENETIC RESOURCES IN THE WILD

The vast majority of the world's genetic resources reside in the South. The mushrooming biotechnology industry, which needs access to those resources, resides largely in the North. Because of the renewed activities by northern MNC's in bio-prospecting in the South, with reported incidents of bio-piracy, the South has been exploring ways of securing due compensation for use of their resources. Bio-piracy extends beyond the taking samples of biota, without compensation to the use of information about the characteristics and medicinal properties of plants, herbs and micro-organisms that reside in the folklore of indigenous peoples.

Erroneously, advocates from the South are demanding intellectual property protection for these resources. The problem is that to

qualify for patent protection a product must be new or novel, it must constitute an inventive step and it must have industrial applicability. Plants occurring naturally in the wild or socially maintained materials or information in the public domain do not qualify for intellectual property protection. There must be human intervention to achieve a result that does not occur in nature (OECD 1996:8) Information in the public domain is freely available to all. Once again, the conflict of basic value systems manifests itself in this problem. Indigenous peoples and traditional farmers innovate in the public domain (Friends of the Earth 1995:15). What is required, therefore, from a Southern point of view, is a new convention that deals specifically with a *sui generis* method of protection for the South's biota and folklore. The concept of developing such a convention has already been accepted by the World Intellectual Property Organization and negotiations will start soon. The onus is on the South, and on the Caribbean, to bring to bear its best minds (legal and scientific) to achieve its objectives in the negotiations.

Some success has already been achieved in the Convention on Biological Diversity that entered into force in 1993. The Convention rejects the notion that the earth's biota is the "Common Heritage of Mankind." Rather, it requires that sovereign rights over resources is respected, that national legislation be developed to conserve and use those resources, and it promotes the equitable sharing of benefits derived from the use of those resources. Access to genetic resources is made dependent on mutually agreed terms of Prior Informed Consent of the owner state. These are broad goals and policies rather than specific targets and obligations, making the convention toothless. The real problem for developing countries is lack of capacity, human and financial, to implement

measures to secure its rights, and there is a need for co-operation by the North in helping the South to monitor activities and derive benefits from the use of its resources.

Some level of co-operation has been achieved in the few cases of bio-prospecting agreements between governments and foreign MNCS; such as the well-known INBio scheme. The Government of Costa Rica and Merck, a multinational pharmaceutical corporation, have an agreement under which Merck is awarded all rights to develop and manufacture any "useful" genetic resources discovered by INBio, a research organization set up by the government composed of scientists working on developmental projects. Merck has paid an up-front fee of US \$1 million for the exclusivity arrangement, and has agreed to pay royalties upon any resultant commercial product (Walden 1996: 181). This arrangement is seen as a model that other developing countries could adopt.

WHO OWNS THE GENETIC MATERIALS IN INTERNATIONAL SEED BANKS?

This issue has become a burning question in the bio-diversity and property rights debate since historically, these seed banks have operated on the basis of giving free and open access to its materials (Platais and Collison 1992:36). Developing countries have been the major contributors to these seed banks, freely supplying samples of their genetic resources over the decades. Once again, the policy was based on community rights, in this case, the welfare of the world community. Now, with the use of the genetic materials by the agro-biotechnology industry for commercial purposes, within the legal

framework of IPR for innovations, developing countries have protested the "open access" policy since it essentially deprived donors of their genetic assets. A struggle has ensued over ownership of these gene banks.

The depository agents for genetic materials are the Sixteen International Agricultural Research Centres (IARC's). The activities of these centres are coordinated by the International Plant Genetic Resources Institute (IPGRI). Forty Public and Private Sector donors have an informal association called the Consultative Group on International Agricultural Research (CGIAR). An agreement was reached in 1994 between the UN, FAO and CGIAR whereby the plant genetic resources in CGIAR gene banks will be held in trust by FAO for the international community. The banks are still operated on the basis of unrestricted use in research on behalf of the international community (OECD 1996: 26). However, Material Transfer Agreements (MTA's) are now in use in some of the IARC's gene banks which require that private organization enter into negotiations with the relevant IARC to determine conditions of use if the germplasm is to be commercially exploited under a protective regime such as patent law. (Walden 1996: 182.) These MTA's seek to secure compensation for the country of origin.

It is generally recognized now that the IARC's must develop new intellectual property policy guidelines for access to materials. (ISNAR, 1992: 32-33). The OECD Study on Intellectual Property, Technology Transfer and Genetic Resources (1996: 27) recognised that IARC's must develop an Intellectual Property Policy since they are operating in a changed funding environment (international funding of these

centres has been drastically reduced) and collaboration with researchers in the private sector would require IPP in order to invite investment. It was suggested in this document that MTA's can be adapted to facilitate equitable collaborative research with, and development of, genetic resources in ways that recognise source-country and local community rights.

Be that as it may, the fact is that developing countries are once more way behind in securing its rights. As far back as 1977, the US Department of Agriculture informed the International Board for Plant Genetic Research (the parent institute to the IPGRI) and the world that the germplasm deposited in their genebank would become the national property of the US (Hingorani 1994: 72).

The UK Plant Breeding Institute sold its genebank to Unilever, one of the world's largest food corporations. As a result, Kenya lost access to the germplasm that it had been depositing in that Institute for decades. As a result of these trends, developing countries are now restricting access to their germplasm. Ethiopia refused to provide Germany with barley germplasm and placed an embargo on its coffee germplasm. Indonesia and Malaysia have been reluctant to share their mango germplasm (*ibid*).

BIO-PROSPECTING AND BIOPIRACY

A concern pre-occupying developing countries is the piracy by northern individuals and corporations of their genetic resources and indigenous knowledge of the uses of these resources to produce and patent commercial products in the North. Numerous cases have been cited of such theft by university professors, corporations

and individuals. For example, products made from the neem tree, traditionally used to make medicines and insecticides in India, have been widely exploited by western corporations and 37 patents have been granted in the US and EU between 1985 and 1995 to use and develop the neem products, largely pesticides. Only three of these patents are held by Indian companies. In Ecuador, there have been several cases of American companies trying to patent traditional medicines and sacred plants. (Agarwal and Narain, 1996).

The latest, highly publicised case is the granting of a patent by the US Patent and Trademark office for the use of the turmeric plant in healing external wounds. This use of turmeric has been the practice in India for centuries, and the Indian Government challenged the patent. The USPTO initiated a process of re-evaluation of the patent claim, but required evidence of 'prior art, by India, deeming acceptable evidence to be in the form of a published academic paper which predates the patent application. India was able to produce such publications (*ibid*), and the USPTO has recently rejected the patent claims, a comforting outcome for developing countries.

However, the nature of the evidence required by the USPTO does not augur well for indigenous communities whose knowledge remains unrecorded, but is handed down verbally through generations. Once again, the rules are those that pertain to the cultural experience of the West. Yet, documenting the knowledge of indigenous peoples without adequate protection of rights of use could lead to more piracy. Moreover, such acts of piracy limit the potential for developing countries to commercially exploit their products in other markets. For the grant of patents for use of neem to make pesticides

means that Indian companies cannot export such products to the US and EU. Also prohibitive to most developing countries is the legal cost of a challenge to a patent: in the turmeric case, it is claimed that the cost to India was \$200,000 (*ibid.*)²

Pirating of samples of biota is also rampant, and extremely difficult to monitor. Biotechnology now makes it possible to secure only a cell sample of a biological resource to achieve the desired end of obtaining the genetic material. It is extremely difficult to detect a minute piece of leaf or cell sample of an animal in luggage leaving a country. The situation is worse for developing countries in that repeated access to those resources may not be necessary once a useful bioactive compound is discovered. In the pharmaceutical context the compound, or structures related to them, may be amenable to chemical synthesis so that commercial production will not always be dependent on the original biological source material (OECD 1996: 28). In the case of crop improvement, once the transfer of a desired gene is achieved, the process of transfer, and therefore access to the original source material never requires repetition (*ibid.*). This makes the task of monitoring by developing countries even more urgent, since, unlike traditional resources required by MNC's such as mineral resources, there is no establishment of presence to mine the resource. Once a gene slips through undetected, there is no way that a country can prove its origin.

² This sum seems excessive. According to the USPTO, the official fee for requesting a re-examination of a patent is US\$2,460. Attorney's fee for preparing documentation for the original request may be around US\$10,000. Cost is also incurred in locating the 'Prior Art'. Thereafter, most of the Attorney's fees would be borne by the patent owner who must respond to any rejection of the patent entered by the examiner.

It is interesting to note the caution to developing countries contained in the OECD document: "Inhibitory conditions of access to the great storehouse of natural or socially maintained genetic resources could further encourage the ongoing search for chemical techniques which might reduce-dependence on bio-prospecting" (OECD 1996:10). The report was referring to a new approach, combinatorial chemistry, whereby computer-aided research can be conducted to identify whether existing synthetic chemical structures housed in chemical libraries can successfully interact with molecular targets underlying the pathology in many diseases. This would give a new boost to synthetically produced drugs.

However, synthetic drugs are in a state of crisis at present because of the development of multi-resistance to antibiotics and the lack of effective anti-infective agents for new diseases that are emerging. Multi-national pharmaceutical companies have been forced to return to the empirical/natural in their R&D, seeking new and natural anti-infectives, to be found in our plants and micro-organisms such as fungi. The accessing of knowledge of the medicinal use of plants and herbs from local and indigenous peoples, with no compensation for the information is minimizing time, expense and effort.

In other words, if developing countries develop effective protective systems that would ensure sharing of profits, MNC's would accelerate the search for ways to do without "lead compounds" found in natural sources through bio-prospecting. This could be a "lose, lose" situation for developing countries: protect the resource and they will find a way to dispense with their need for it; don't protect it and they will exploit the free

access to it. This depends on the success of R & D in combinatorial chemistry, however.

FOOD SECURITY

Food security and bio-diversity are threatened by the increasing use of patented seeds and protected plant varieties. The very fact that the criteria for protection are uniformity and stability means that species diversity is being eliminated. This is totally contrary to traditional farming practice whereby a variety of species are deliberately planted in order to prevent total crop loss in the event of attack by pest or disease, presuming that some varieties would have resistance. With a uniform variety constituting the whole crop, one pest or disease attack could wipe out the entire harvest if the variety is susceptible. It also means that *in situ* conservation, that is a direct result of traditional farming, will be reduced, threatening biological diversity.

The breeding of essentially derived varieties only upon payment of royalty could be a disincentive to the adaptation of protected varieties to local conditions in developing countries. MNC's usually produce to suit the conditions in their home country, and then mass-produce the product since adaptation to differing local conditions would increase cost. This may create problems for producers in developing countries who use non-adapted varieties (Friends of the Earth 1995: 18-19).

BIOSAFETY³

Bio-technology industries need to test their products, and in many cases this means using the human, animal or natural environments as

³ The testing and release of genetically altered plant varieties in farmer's fields.

their laboratory. But once genetically modified organisms (GMO's) are released into these environments, there may be no means to recall or inactivate them if there are deleterious consequences. There may even be long-term harmful results that are yet unknown. GMO's may, for instance, multiply and become uncontrollable pests, spreading to weeds and transferring resistant genes. Further, mutation of released organisms may cause incurable diseases or even indestructible predatory organisms. Human genetic vaccines can have catastrophic consequences if patients react adversely to them since their bodies will continue to produce the vaccine (Hingorani 1994:69). Potential out-crossing with wild relatives is one of the major bio-safety concerns for GMO's. Since the majority of centers of diversity for food plants are in developing countries, a proper risk assessment is even more important for developing countries than for industrialised countries (ISAAA 1995:4).

It is important to note that the biotechnology industry is largely controlled by the private sector, not government research institutions. This makes monitoring and control of activities difficult for government officials. Society therefore has to rely on these MNC's to be responsible. There is growing evidence that developing countries are being used by private sector companies as laboratories for release of GMO's (Plataist Collinson; 1992:36). For instance, Wistar Institute in Philadelphia released a genetically engineered vaccine for rabies into cattle in Argentina. The foreign scientists did not inform local scientists or the government of the risks. Both agricultural workers and the cattle developed antibodies to the virus. Little is known about the process that occurred (Hingorani 1994: 69).

Strict biosafety regulations need to be developed and applied quickly in developing countries. Systems and guidelines need to be developed to assess data and information and evaluate risks. There is also need for both national biosafety agencies and a specialized institutional biosafety committee on risk management (ISAAA 1995:4). Drawing on the experience of other countries and strengthening co-operation between countries can do this most effectively. There are many national and international initiatives on biosafety in progress, such as the OECD guidelines, the EC Directive on containment and release, the Inter-American Institute for Cooperation on Agriculture guidelines for field releases in Latin America (ISNAR 1992:5). There is the view, however, that the issue of bio-safety is being exaggerated, that biotechnology represents a continuum of techniques which people have practiced throughout history, and if the GMO's and techniques adopted are well understood, the predictability of the end product 's behaviour would be high and the risk involved in its use would be minimal (*ibid*).

CONSTRAINTS FOR DEVELOPING COUNTRIES

Hingorani (1994: 76) argues that in order to be competitive in the bio-technology industry, a country must have synergy between new bio-developments, micro-processing, marketing and distribution. Most developing countries do not have this industrial structure and therefore lack this synergy. There is a lack of information and technological and administrative know how to monitor and control the release of GMO's. Poverty has driven landowners in Latin America to allow their farms to be used for unauthorized field experiments in biotechnological innovations (*ibid*).

A basic rationale given in support of strong intellectual property protection is that it would stimulate innovation and this would generate economic growth, benefiting the national society. There is the presumption that strong protection by itself would yield these results. The experience in developing countries has been different - little indigenous innovation has resulted and foreigners, largely to protect their imports (< biblio >) have secured most registered patents. In developing countries, markets are often too small to be viable and research is conducted by the public rather than the private sector. Local investors prefer "available" technology, which involves less cost and less risk (ISNAR 1992:4).

According to Platais and Collinson (1992:34), developing countries are divided into two groups: those with potential to adapt imported biotechnology to local conditions (Brazil, China, India, Thailand); and those with little or no applied research capacity, to exploit imported technology (the rest). The first group has this capacity as a direct result of concerted efforts among policy-makers and scientists to develop national biotechnology policies. Yet, they still face constraints of shortage of investment capital and lack of trained scientists.

Indeed, what seems to be happening is a reinforcement of the traditional international division of labour by producing protected seeds in the North and sowing and harvesting them in the South using cheap labour. There is the example of the Royal Sivils Company, a Dutch seed company, that is producing the seeds at home, and planting and harvesting in Tanzania with cheap labour. The harvested seeds are sent back to the Netherlands and re-exported. (Hingorani 1994: 74). Moreover, biotechnology

products are threatening the viability of traditional exports by becoming substitutes, e.g., as replacement of animal feed protein, sugar and gum arabic. Most developing countries would be negatively affected by this development: Brazil & Argentina's soybean trade, Ivory Coast peanuts, Sudan, Kenya, Tanzania and Ecuador for gum arabic (ibid).

SOME CURRENT STRATEGIES AND PROGRAMMES TO HELP DEVELOPING COUNTRIES

While there may be several programmes currently being pursued to help developing countries deal with the rapidly changing conditions for competitive production in agriculture, two are referred to in this paper. The first is the strategy being adopted by CGIAR and the second is the work by International Service for the Acquisition of Agri-biotech Applications (ISAAA).

CGIAR's strategy is to draw on tested biotechnology techniques from advanced research laboratories and apply them to existing research activities, rather than undertaking innovative biotechnology research themselves, given the small scale of their operation.⁴ They have developed a network linking laboratories in Japan, Europe, the US and Australia with two CGIAR centres, the International Rice Research Institute in the Philippines and the Centro Internacional de Agricultura Tropical, (CIAT) in Columbia. They have also developed a Cassava Biotechnology Network involving CIAT, the International Institute for Tropical Agriculture and scientists in Latin America, Africa, Europe

⁴ In 1990, CGIAR invested \$14.5m in R&D while worldwide investment was \$11 billion.

and the US. This grouping focuses on problems associated with Cassava biochemistry through molecular research. This work is important since the focus of agri-biotechnology has been on products that are commercially important to multinational corporations and not the less economically attractive but important food crops unique to developing countries, that is, orphan commodities (Platais and Collinson 1992:34-36).

ISAAA's work is centered on organizing projects that would effect technology transfer from corporate leaders in R & D for the benefit of small farmers in developing countries. Among such projects are the joint efforts by Mexico and Monsanto to develop virus-resistant potato, and cooperation between Brazil and Pioneer Hi-Bred International to identify the pathogens causing corn stunt. ISAAA's work needs to be examined more closely as that Institution offers the possibility for technical assistance in developing Material Transfer Agreements as well as effective technology transfer. ISAAA also offers human resource development programmes.

IMPLICATIONS FOR THE CARIBBEAN: QUESTIONS

Much needs to be understood about the Caribbean's position vis a vis intellectual property protection and technology transfer. We need, urgently, to evaluate our situation and take measures to protect our research and germplasm. There are several questions that need to be asked. At this stage, these centre primarily around ownership of our biota, access to technology, and what will be the effects on our agriculture of the new rules for use of protected reproductive materials and seeds.

In terms of our natural biological resources, stringent national laws are needed to restrict free access to these materials. Some countries have already started that process. Caribbean countries need to actively take part in the WIPO negotiations on protection of folklore. We also need to develop biosafety regulations urgently, so as to protect our environment.

The system for conservation of genetic material undertaken in the region, or contribution to seed banks needs to be examined to ensure protection of property rights. For instance, one needs to question the policy of access to germplasm from the Cocoa Research Unit, which operates in Trinidad and Tobago.

Cocoa seeds cannot be preserved *ex situ* because they are subject to desiccation in combination with low temperatures. *In situ* conservation is therefore necessary. The International Cocoa Genebank maintained by the Cocoa Research Unit conserves nearly 2,500 accessions in its field collection. It is the most genetically diverse cacao germplasm collection in the world. Specimens are sent to a quarantine station at Reading from where they are re-distributed to cocoa research centres in various countries. A total of 202 accessions have so far been transferred to the Reading Station (CRU Reports 1994-1997). At present, the CRU is not informed about where these accessions go. The recipients are invisible, and the CRU is given no credit. It is possible for a private corporation to access the genetic material without cost and with the minimum of alteration, patent a variety. It is also possible that synthetic substitute could be produced. We should therefore examine the policies relating to access to the material.

Further research is needed in the area of access to our genetic material, technology acquisition and assimilation and the effect of the protection of seeds and reproductive materials on our farmers and plant breeders. Consideration has to be given to the protocol governing dissemination of academic research, since publication of research findings eliminates the possibility of obtaining a patent in the US. This will be the focus of the continuing work on this paper.

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