

Trade, Intellectual Property, Food and Biodiversity

Key issues and options for the 1999 review
of Article 27.3(b) of the TRIPS Agreement

A Discussion Paper

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Preface

There is a growing debate about intellectual property rights, food, farming, biodiversity, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) and other agreements. This paper aims to draw on the various perspectives presented in the body of literature informing debate to:

- highlight, clearly and concisely, the policy questions raised for developing country governments by Article 27.3(b) of the TRIPS Agreement, in particular those concerning food security, and the options for the review of its provisions
- examine the key ethical, economic, environmental and social issues surrounding its provisions - and their relation to other international negotiations
- consider the possible contributions of overseas development assistance.

This paper is written for policy makers, primarily in developing countries, in agriculture, environment and trade and those responsible for ensuring policy coherence across government departments. By outlining the differing perspectives surrounding this key clause dealing with patents and other intellectual property rights over plants, animals, micro-organisms and new plant varieties, and highlighting the various sources and technical materials available, we aim to contribute to informed public debate about, and policy making concerning, this issue.

The Environmental Intermediaries (EI) Programme of Quaker Peace & Service (QPS) links traditional Quaker concerns for peace and justice with a concern for the environment. In 1999, the Quaker United Nations Office (QUNO) in Geneva will carry out part of the EI Programme work seeking to strengthen the capacity of developing countries to safeguard the interests of their people and to bring these countries into dialogue with industrialised countries around issues raised by the review of Article 27.3(b).

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Executive Summary

This discussion paper reviews the complexities and uncertainties surrounding the impact of the current multilateral Intellectual Property Rights (IPRs) regime, on plants and animals, on plant variety protection systems, and on food security and agricultural biodiversity. These ambiguities caution against any strengthening of such rights at this time. The polarised debate about the ethical, economic, environmental and social effects of IPRs, especially patents, needs to be informed by hard evidence gathered through case studies and impact assessments carried out in a range of different countries. Countries may, therefore, want to keep their options open in relation to the provisions of Article 27.3(b) of the TRIPS Agreement and avoid any narrowing of the options for IP protection in the foreseeable future.

Section 1 briefly examines the nature of IPRs, their origin and role in market economies, and the balance they represent between providing incentives to create knowledge and the desirability of disseminating knowledge freely for everyone's benefit. It explains the complexities of assessing the effects of IPRs in developing countries and outlines the potential opportunities and challenges that IPRs offer them, in particular concerning the use of patents over lifeforms and in restraining the anti-competitive effects of IPRs.

Section 2 examines the clause in the TRIPS Agreement - Article 27.3(b) - that permits exceptions from patentability for plants, animals and biological processes, and includes the requirement for a *sui generis* system of IP protection for plant varieties or use of patents or both. It outlines the implementation requirements, includes views on patents, on the existing *sui generis* system of the International Union for the Protection of New Varieties of Plants (UPOV) and on alternatives to this as well as the fiscal, legal and market implications of these.

The key issues for the 1999 review of Article 27.3(b) are considered in *Section 3* - its scope, review options, the different positions being taken by various countries, and the relationship between the review and other international obligations, notably those under the Convention on Biological Diversity (CBD) and International Undertaking on Plant Genetic Resources (IU). The need for national policy coherence is highlighted together with ways to achieve it. These include rapid assessments of the potential impact in local communities, a survey of all the relevant work of different ministries and agencies, regional consultations and an inter-ministerial working group or similar coordinating process.

Section 4 looks at the broader picture - the moral and ethical issues raised by patents over lifeforms, the nature of invention and clashes with different cultural and beliefs systems; the balance between individual private rights and communal, public rights; the risks to democracy; and, the lack of equity in the international negotiations. In economics, the issues of technology transfer and R&D priorities are highlighted while the environmental issues spotlighted are those relating to the links between patents and the rapid development of genetic engineering. Finally, the potentially socially disruptive effects on local farming systems through rapid changes in the economic structure are also noted.

The potential for practical short-term assistance in the review process and some longer-term issues for Official Development Assistance (ODA) are raised in *Section 5* before brief conclusions and recommendations in *Section 6*. These urge provision of short-term policy development assistance for developing countries, both in capitals and in Geneva, as well as suggestions for wide-ranging national stakeholder consultations on the issues raised by IPRs protection on lifeforms.

The bibliography lists the key source materials used, together with details of how to obtain them.

1. Intellectual property, food and farming

IPRs - rights granted by a state authority for certain products of intellectual effort and ingenuity

Sui generis system of rights is an alternative, unique form of intellectual property protection, designed to fit a particular context and needs

“A country where innovation is not a major source of economic activity and growth is likely to choose, on balance, a less stringent intellectual property regime than would a country whose economy is highly dependent on innovations.”

Trebilcock and Howse, 1998, p 251

One of the many agreements annexed to the agreement setting up the World Trade Organisation (WTO) is that on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Article 27.1 of this agreement requires Members to provide for patents “for all inventions, whether products or processes, in all fields of technology”. Article 27.3(b) allows them to exclude from patentability plants and animals but not micro-organisms. It also requires them to provide for the protection of new plant varieties using patents, or an effective *sui generis* system, or a mixture of both. This Article has caused controversy in both developing and industrialised countries and the negotiators included the requirement to review its provisions in 1999. This will be done by the Council for TRIPS at WTO.

The focus of this paper is on the implications of Article 27.3(b) for food, farming and agricultural biodiversity - the basis of humankind’s future food security. The issues surrounding the pharmaceutical use of plants and animals are not considered here but deserve equal attention.

Intellectual property rights (IPRs) are part of the institutional infrastructure of market-based economies and affect the dynamics of innovation (Box 1). They include copyright, patents and trade secrets. IPRs provide inventors with protection from someone copying or using their work or invention without permission. IPRs need to be tailored to the technological materials to which they relate as well as the socio-economic environment in which they operate if they are to be effective.

1.1 The IPRs trade-off

“IPRs are a compromise between preserving the incentive to create knowledge and the desirability of disseminating knowledge at little or no cost”, notes the World Bank’s World Development Report 1998/99¹. In theory, stronger IPRs should encourage more research and development (R&D) in countries where they exist, but there is “limited empirical evidence” even in industrial countries that IPRs protection leads to increased investment in R&D. This is partly because of the difficulty of separating cause and effect - IPRs may stimulate more investment, but countries that invest more in R&D may demand more protection.

Although IPRs restrict direct imitation, they can assist in the diffusion process of new knowledge within and between economies. Patents provide published information which other researchers can also use to develop innovations (Box 2). The Bank found that the level of IPRs protection appears to influence the degree of foreign direct investment (FDI), the vertical integration of multinational firms, and direct

¹World Bank, 1998, p 33

1. The concept of intellectual property

The basic concept of intellectual property can be traced back as far as the fourth century BC to Aristotle. Two main moral and philosophical arguments for rewarding innovators have been used. One stems from Hegel - that an idea belongs to its creator because the idea is a manifestation of the creator’s personality or self. The other from Locke - that the unpleasantness of labour should be rewarded with property.

In today’s market-based economies, however, the rationale for protecting intellectual property is essentially utilitarian. A piece of knowledge -

whether the blueprint of a new machine or a new method of harvesting wheat - unlike a physical object can be used by one person without limiting its use by others. The widest possible dissemination of new knowledge, then, makes for the greatest economic efficiency. But if everybody is free to access new knowledge, inventors have little incentive to commit resources to producing it. IPRs (temporarily) transform knowledge from a public good into a private good. Through enhanced market power conferred by the IPRs title, owners of intellectual property can recoup their expenditure in creating new knowl-

edge. Creative minds and innovative firms thus have an incentive to engage in inventive activities.

This utilitarian argument provides the main rationale for the protection given by patents, copyright, plant breeders’ rights and several other types of IPRs. The various forms of intellectual property differ in terms of the subject matter that may be eligible for protection, the scope and duration of protection, and possible exemptions to exclusive rights - reflecting society’s objective to balance the interests of producers and users of intellectual works.

Sources: Primo Braga 1990, Primo Braga et al, 1999, and Downes, 1998

2. Patents

A patent prevents someone from making commercial use of what is claimed in the patent without the authorisation of the patent holder. To be patentable, an invention must be:

- non-obvious for someone skilled in the art, i.e. not simply be an extension of something that already exists but require some inventive step;
- novel, i.e. not previously known; and,
- industrially applicable in some way.

Patents can be given for products and processes. Patents are limited to a fixed period – at least 20 years under TRIPS – after which the invention moves into the public domain and can be used by anyone. They only apply in the country in which they are granted. In return for the temporary partial

monopoly granted by the patent, the inventor must make a full disclosure of the nature of his invention understandable to anyone else skilled in the necessary arts or sciences. In this way, inventions do not “die with the inventor”. Moreover, others can try to invent something better, but sufficiently different, so as not to infringe the claim of the original patent.

Clear evidence that the patent system has stimulated the development of new products and technologies, which otherwise would not have been developed, is only available for a few sectors (such as pharmaceuticals). In other sectors, patents are sometimes considered to have mainly anti-competitive effects: they serve to secure and strengthen the position of market leaders and limit the entry of new competitors*. In the

extreme, they may actually slow the pace of innovation if a dominant firm possesses a powerful pool of patents that limits the ability of other firms to further improve existing products and technologies.

Although policymakers have sought to limit such adverse effects of patents through revised IPRs legislation, competition policy, and other business regulations, the anti-competitive implications of patents remain a cause of concern. Such concerns have regained momentum with the emergence of patents on biotechnology products and processes that cover fundamental research tools, genetically-engineered plants, human genes, and even living organisms.

* Jenkins, 1975, gives an historical example. Source: Primo Braga et al, 1999

“IPRs...do not assure a return; in fact only up to 15 percent of patents are ever commercialised... All financial rewards come from market sales. Hence key factors such as breadth (scope) of protection and enforcement are critical in determining the practical value of IPR[s]”

Lesser, 1997, p 4

technology transfers through technology sales and licensing agreements, although the relationship between protection and FDI is not well established according to other studies².

There are costs related to the granting of IPRs. They increase the market power of right's owners which may lead to higher consumer prices. They also “shift bargaining power toward the producers of knowledge, and away from its users” says the Bank. Stronger IPRs may lead to a higher cost of acquiring knowledge and so may adversely affect follow-on innovations that draw on inventions whose patents have not yet expired. Tighter IPRs, notes the Bank, “may actually slow the overall pace of innovation. However, there is no systematic empirical evidence confirming this, just as there is none on the positive impact of IPRs on increased R&D”³.

Policy-makers face the difficult task of defining the scope of IPRs - the length and breadth of protection - so as to maximise social welfare and to achieve certain distributional objectives (Box 3). Too weak protection may lead firms to invest less than socially desirable in the creation of new knowledge. Overly stringent protection may lead to wasteful R&D spending as firms compete to be first to innovate which may make public R&D more socially desirable than private R&D. Only rarely will “a single level of protection for all technologies or sectors maximise domestic welfare” as the trade off between the economic benefits of innovation and imitation will depend upon the sector involved⁴.

Overall, the economic effects from stronger IPRs are far from simple, clear or agreed. However, companies will not use genetic engineering to modify plants and animals unless they can recoup their investment in research and product development. IPRs were developed for manufactured goods, where companies can expect repeat business as fashions change or items wear out. New varieties and many biotech goods, however, are living organisms which can reproduce themselves and so may not require repeat purchases. To ensure a return on investment and a future income stream from these inventions, companies want IPRs, especially patents, to be extended globally to cover the original material and subsequent generations of newly-invented life forms such as new plant varieties. An alternative for some crops may be to breed varieties that will not reproduce. Researchers in the USA and UK have patented ways to make plants produce seed that will not germinate. Such seeds would not require legal agreements or enforcement officers to stop farmers reusing them.

1.2 IPRs in developing countries

The effects of IPRs protection become even more complex when producers and users of knowledge are in different countries with different economic levels of development. Theoretically “it is far from clear that all countries should be required to

² UN, 1993

³ World Bank, 1998, pp 34-5

⁴ Trebilcock and Howse, 1998, p 250-51

“Companies now seek protection through IPR in more countries than they did in the past in order to (i) expand their market share, (ii) prevent competitors from becoming active in those countries, or (iii) as a bargaining tool to negotiate favourable local agreements.”

van Wijk et al, 1993, p 10

maintain the same level of intellectual property protection” argue Trebilcock and Howse. If a country has limited innovative capabilities and primarily consumes foreign innovations, they suggest stronger IPRs protection may lead to “at least short-term consumer welfare losses and may discourage imitation and adaptation by competitors, which themselves constitute valuable economic activities”. For example, in some developing countries with patent systems, patent protection was not allowed on certain products, such as pharmaceuticals. The absence of patents enabled their infant industries to examine and copy products and develop local production capacities - as Swiss industry did in the 19th century⁵. This may have inhibited inward investment but it may also have produced net economic benefits for the country.

Professor Lester Thurow of MIT’s Sloan School of Management argues that the experience of economic history is that “copying to catch up is the only way to catch up”,⁶ but others believe that this is overstated. Moreover, a large share of knowledge “needed” in developing countries (especially the poorest ones) is in the public domain and not covered by IPRs (including for agriculture)⁷.

The Bank suggests IPRs can disadvantage developing countries, however, “by increasing the knowledge gap and by shifting bargaining power toward the producers of knowledge, most of whom reside in industrial countries”⁸. While accepting the point, some see such a view of IPRs as equating knowledge producers with commercial and research-based producers. They focus more on the role played by farming communities in developing countries in producing knowledge about plants and animals⁹. Given the many dimensions to IPRs and that changes in them may affect developing countries in different ways, these effects should be taken into account as such agreements evolve, suggests the Bank.

It sees IPRs as offering an opportunity giving the private sector a greater incentive to develop products useful for developing countries, such as drugs against tropical diseases that have been neglected by the pharmaceutical industry. Stronger IPRs may also increase incentives for local research although developing countries do not have the same traditional reliance on IPRs as is common in most developed countries¹⁰. Many countries also lack an accountable legal infrastructure and organisations that effectively administer and enforce IPRs.

IPRs also pose developing countries with a challenge because “so many industrial-country firms are acquiring strong intellectual property positions, often covering fundamental research tools as well as marketable products, that it may prove hard for new firms and researchers to elbow into this new global industry”. Both firms and public research groups need to be able to negotiate agreements to use these technologies and “to participate in the continuing debate about particular forms of intellectual property, to ensure that their interests and those of their country are taken into account”¹¹.

⁵ Gerster, 1998

⁶ Thurow, 1997, pp 95-103

⁷ Primo Braga et al, 1999

⁸ World Bank, 1998, p 35

⁹ Tilahun and Edwards, 1996

¹⁰ Lesser (1997) notes that for IPRs to be socially acceptable in the West required a society secularised enough to accept that creative genius was a personal trait not a divine gift, that intellectual products had to have commercial value in their own right and that private rights had to be distinguishable from those of sovereigns. (p 11)

¹¹ World Bank, 1998, p 35 + pp 35-36

3. IPRs and competition

IPRs affect competition in various ways. The grant of an IPRs title confers market power on the rights holder as competitors are not allowed to copy the protected technology or product. In most cases, however, IPRs ownership does not lead to a perfect monopoly in the underlying market. Typically, with a patented product for example, it competes with other products or technologies which themselves may or may not be covered by patent rights. If the patent holder raises prices by too much, consumers may decide to switch to substitute products that may not offer the exact same features as the patented good, but may nonetheless satisfy their needs. Firms in markets that are covered by IPRs engage in what econo-

mists call monopolistic competition. One factor determining prices in a monopolistically competitive market is how far one product can be substituted by another product.

In time, IPRs can promote a dynamic process of competition. A patent, for example, gives a firm the ability to gain market share, but once this firm has established itself as market leader, competing firms try to invent better technologies, obtain patents themselves, and squeeze the market leader’s position. Consumers may temporarily pay higher prices for patented products, but may also benefit in the long run if dynamic competition leads to a continuous stream of innovations and significant price falls in the older products.

For this to happen, however, governments must prevent potential anti-competitive practices of firms owning IPRs including:

- cross-licensing of IPRs among market leaders that fix prices or divide markets (cartel-like behaviour);
- restrictive vertical licensing agreements with tie-in sales or obligations on the use of proprietary technology;
- purchase of competing patents leading to horizontal mergers; and,
- predation of market entrants by threatening law suits.

Countries adopting new IPRs regimes, therefore, need to develop effective competition regulations.

Source: Primo Braga et al, 1999

2. The TRIPS Agreement and Article 27.3(b)

Article 27.3(b)

3. Members may also exclude from patentability: ...

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

“*ordre public*” concerns the fundamentals from which one cannot derogate without endangering the institutions of a given society....Morality is a different concept”

Gervais, 1998, p 149

The TRIPS Agreement is the result of intense negotiations and a compromise between different sets of interests. It provides minimum national standards for levels of protection to the creators of intellectual property. It covers:

- copyright and related rights;
- trademarks;
- geographical indications;
- industrial designs;
- patents (and plant variety protection or PVP);
- layout-designs (topographies) of integrated circuits;
- protection of undisclosed information; and,
- control of anti-competitive practices in contractual licences

in the part (II) that deals with standards concerning the availability, scope and use of IPRs¹². Patents and PVP are the most important areas for agriculture.

The TRIPS Agreement is one of the three pillars of the WTO - the others being trade in goods and trade in services. By placing IPRs in the WTO and making them subject to its binding disputes procedure, proponents of a strong IPRs regime have made it possible for non-compliant WTO Members to face trade sanctions in any area if they fail to live up to its rules. This is arguably the main reason why IPRs were put into WTO instead of the existing body promoting IPRs, the World Intellectual Property Organisation (WIPO). The TRIPS Agreement also includes for the first time in any area of international law “rules on domestic enforcement procedures and remedies”¹³. The whole TRIPS Agreement is due to be reviewed after January 2000.

2.1 Patents on lifeforms

The key element of the TRIPS Agreement for food and farming is the requirement for WTO Members to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination. One reason for greater interest in patents is the rapid development of biotechnology, especially in the OECD countries, and its application in agriculture. Apart from Article 27.3(b) - see margin - two other Articles permit exceptions to the basic rule on patentability:

1. When members want to prevent the commercial exploitation of the invention to protect *ordre public* or morality; this explicitly includes inventions dangerous to human, animal or plant life or health or seriously prejudicial to the environment (Art 27.2).
2. Diagnostic, therapeutic and surgical methods for the treatment of humans or animals (Art 27.3(a)).

Members may also provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties (Art 30).

Patents must also be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced - the so-called ‘national principle’ (Art 27.1). According to Article 28.1(a) of the TRIPS Agreement, patents relating to products confer the right to prevent third parties from “making, using, offering for sale or importing for those purposes the product” without the patentee’s consent.

In the case of process patents, the patentee may prevent the use of the process as well as the commercialisation of a product “obtained directly by that process”. Thus, if a process to produce a plant (e.g. by genetic engineering) is patented, exclusive rights would also apply with respect to the plants obtained with the process. Article 34.1 also places the burden of proof in process patents on the producer to show that it is not being produced by the patented process¹⁴.

¹² WTO, legal texts, pp 370-386

¹³ Geuze, 1998

¹⁴ Dhar, 1998

Much of the current debate focuses on plants - largely because of the requirement to provide some form of IPRs for plant varieties if WTO Members exempt plants and animals from patents. However, there is much biotech animal research going on with many patents being taken out by those involved where it is permitted. Recently patents have been awarded in the USA on DNA sequence tags, which are fragments of genes. This could result in various companies holding ownership rights over different parts of one gene and agreement from each of these being required, with possible royalty payments, to work with these genes in countries where patents are provided for. Since some of these fragments cross species where there is some common structure in some basic genes, rights owners could have a wide-ranging control of use of such transgenes in animal research and breeding.

2.2 Article 27.3(b)

The TRIPS Agreement is a legal text subject to interpretation and legal argument over its precise meaning. The terms used in Article 27.3(b) are not defined in the TRIPS Agreement. Various authors argue that this means there is considerable scope for individual national interpretations to be put onto them and protracted legal wrangles are likely to determine which ones will prevail. Several authors have made detailed examinations of the issues, notably Dan Leskien and Michael Flitner for the International Plant Genetic Resources Institute (IPGRI), Carlos Correa for FAO and Biswajit Dhar from the Research Information System for the Non-Aligned and Other Developing Countries (RIS) in India, and their studies are extensively used in what follows.

'When I use a word,' Humpty Dumpty said in rather a scornful tone, 'it means just what I choose it to mean — neither more nor less.'

'The question is,' said Alice, 'whether you can make words mean so many different things.'

'The question is,' said Humpty Dumpty, 'which is to be master -- that's all.'

From: *Through The Looking-Glass - And What Alice Found There*, by Lewis Carroll

The words that are open to interpretation are:

- plants,
- animals,
- micro-organisms,
- essentially biological processes,
- non-biological,
- microbiological,
- plant varieties,
- effective, and
- *sui generis* system,

although the degree to which they are, is disputed. These words are defined differently in different international and national legislation. It is unclear what meaning will prevail until either they are specifically defined in WTO or differing interpretations are argued in the dispute settlement procedure and specific definitions arrived at through the judicial process. However, it is open to countries to record their interpretations before the Council for TRIPS and this may be useful should disputes arise.

2.2.1 Implementation requirements

WTO Members must ensure their laws meet the minimum standards laid down in the TRIPS Agreement but they can introduce tougher laws if they wish. They do not, however, all have to comply at the same time (Art 65):

- Developed countries had to implement TRIPS within one year of entry into force of the Agreement.
- Developing countries had an extra four years - i.e. by 1 January 2000¹⁵.
- Economies in transition (from centrally-planned to market economies) also had an extra four years - i.e. to 1 January 2000.
- Least developed countries have a 10 year transition period but they may apply for extensions to this (Art 66.1).

Newly acceding members of the WTO do not benefit from the transitional arrangements but must comply with the TRIPS obligations immediately they join the organisation.

Four options are consistent with the obligations in Article 27.3(b):

1. To allow patents on everything, and not to take up the option to exclude plants, animals and essentially biological processes.

¹⁵ If developing country members have to "extend patent protection to areas of technology not so protected in its territory", they have a further five years to apply the provisions on product patents. However, transitional arrangements (Arts 70.8 and 70.9) apply to pharmaceuticals and agro-chemicals

Essentially biological processes - in plant biotechnology these can include multi-step processes consisting of the genetic modification of plant cells, the subsequent regeneration of plants and the propagation of these plants. Some definitions are more restrictive: “any process which, taken as a whole, exist in nature or is not more than a natural ... breeding process.”

Patent on a product or process confers an exclusive right on its owner to prevent a third party from making, using, offering for sale, selling or importing that product or a product obtained directly from that process, without the owners' consent

Inventive step - not obvious, having regard to the state of the art, to a person skilled in the art

Novelty - the state of the art comprising everything made available anywhere to the public by means of written or oral description, by use, or in any other way, before the date of filing of the patent application.

2. To exclude plants, animals and essentially biological processes from patenting but not to exclude plant varieties from patentability.
3. To exclude plants, animals and essentially biological processes from patenting and to introduce a special *sui generis* right for the protection of plant varieties.
4. To exclude plants, animals and essentially biological processes from patenting but not plant varieties and to provide, in addition, for a *sui generis* right (“combination thereof”).

Options 1 and 2 do not require Members to establish a *sui generis* system to protect plant varieties.

2.2.2 The patent option

Extending patentability to lifeforms is a controversial issue (see *Section 4*). Currently “patenting principles and practices on biotechnological inventions are still in a state of flux, including in those countries that have already gained experience in patenting genes,” says Prof Correa. In plants, patents may apply to a variety of biological materials and processes, including:

- isolated DNA sequences that code for certain proteins;
- isolated or purified proteins;
- seeds;
- plant cells and plants;
- plant varieties, including parent lines;
- hybrids;
- processes to genetically modify plants; and,
- processes to obtain hybrids¹⁶.

“The patenting of genes at the cell level extends the scope of protection to all plants which include a cell with the claimed gene”, he says.

Generally speaking, patents give patentees the right to prevent any commercial use of the materials, including for research and breeding purposes. This could threaten commercial breeding, especially with broadly drafted patents, for example, those which seek rights over processes used in any species. Unduly broad patents, however, should not be granted and, if they are, may be revoked following successful legal action.

WTO Members may provide limited exceptions to the exclusive rights conferred by a patent (Art 30). This provides some flexibility in drafting patent legislation and may allow Members to include exemption for research and breeding purposes. WTO Members are also free to determine what ‘invention’ means and many developing countries, including Argentina, Brazil and the Andean Pact countries, “exclude the patentability of materials found in nature, even if isolated therefrom”, notes Prof Correa. Other areas of flexibility are in how novelty and inventive step are interpreted and the scope of claims that will be admitted.

2.2.3 The *sui generis* system option

A *sui generis* (of its own kind) system of protection is a special system adapted to a particular subject matter, as opposed to protection provided by one of the main systems of intellectual property protection, e.g. the patent or copyright system. A special law for the protection of integrated circuits is an example of a *sui generis* law. In this case, it means countries can make their own rules to protect new plant varieties with some form of IPR provided that such protection is effective. The Agreement does not define the elements of an effective system. In the last resort it will be a WTO Dispute Settlement Panel which will interpret the provision under the procedure for the settlement of disputes .

One possible *sui generis* system likely to be recognized as effective is the UPOV system of Plant Breeders' Rights (PBRs). This initially developed in Europe, has now been adopted by the industrialised countries, and is also being adopted by an increasing number of developing countries (Boxes 4&5). PBRs were developed because plant breeders found it difficult or impossible to meet two of the fundamental requirements of patent law: inventiveness, and a written description of how to make and use¹⁷. The UPOV system, however, produces a quite strong IPRs regime for plant

¹⁶ Correa, 1998

¹⁷ Tim Roberts, personal communication

4. UPOV

The International Union for the Protection of New Varieties of Plants (UPOV) adopted its first Convention in 1961 after four years of meetings between various European states. It has been revised three times since in 1972, 1978 and 1991. The main aims of the Convention are to promote the pro-

tection of the rights of breeders of new plant varieties and the development of agriculture. The modification of the Convention in 1991 sought to maintain the effectiveness of breeders' rights in the face of changing technologies. This led to the introduction of stronger terms which are now the only terms under which new members may join. A key addition was designed to prevent genetic engineers from adding single

genes to existing varieties and exploiting the modified variety with no recognition of the contribution of the breeder of the existing variety. Such modified varieties are now seen as 'essentially derived' varieties and may not be exploited without the consent of the original breeder. The main provisions of PBRs in UPOV 78 and 91 compared to patents are given below.

Provision	UPOV 1978 Act	UPOV 1991 Act	Patent Law
Protection coverage	As many plant genera and species 'as possible'. Minimum of 5 on joining and of 24 after 8 years	Minimum of 5 on joining. 10 years later, must protect all plant genera and species	Inventions
Requirement	Novelty (variety must not have been commercialised) Distinctness Sufficient Uniformity having regard to the particular features of variety's propagation Stability	Novelty (variety must not have been commercialised) Distinctness Sufficient Uniformity having regard to the particular features of variety's propagation Stability	Novelty (invention must not have been published) Non-obviousness (inventiveness) Industrial applicability (usefulness)
Protection term	Minimum 15 years (18 years for trees and vines)	Minimum 20 years (25 years for trees and vines)	Minimum 20 years (TRIPS)
Protection scope	Production for commercial purposes and offering for sale and marketing of propagating material of the variety	Commercial transactions with propagating material. Harvested material protected only if produced from propagating material without breeder's permission and if breeder had no reasonable chance to exploit his right over it	Making, using, selling patented product; using patented process
Breeders' exemption	Yes	Yes. <i>Essentially derived</i> varieties can only be marketed with the agreement of the breeder	No
Farmers' privilege	Minimum scope of protection allows a farmer's privilege	Each member State can define a farmer's privilege suitable for its conditions	No
Prohibition of double protection	Any species eligible for PBR protection can not be patented	The Act is silent on this question; countries may choose to exclude plant varieties from patent protection	Many countries exclude plant varieties, as such, from patent protection

Source: Original table van Wijk et al, p 8, updated by UPOV secretariat

varieties geared to institutional breeding which may not suit all countries.

The alternative is for countries to develop their own solution with special legislation protecting plant varieties appropriate to their situation. Both are possible but developing an appropriate *sui generis* system is a challenging task that may take some time. Although many countries are working on such legislation, none is currently in place (Box 6). Leskien and Flitner suggest "countries have considerable room to develop their own system" in defining a *sui generis* system¹⁸. Basically, to be in keeping with TRIPS the system should:

1. Provide a legally enforceable right that either excludes others from using the protected plant variety, or enables owners to be paid for certain uses of the plant variety by third parties.
2. Treat nationals of other WTO member states no less favourably than their own nationals for the protection of plant varieties.
3. Provide any advantage, favour, privilege or immunity granted by a member state to the nationals of any other country immediately and unconditionally to the nationals of all the other member states (most-favoured-nation treatment).
4. Include an enforcement procedure capable of acting against any act of infringement of the *sui generis* right¹⁹.

Countries must define what the scope of the system will be. This must cover:

1. What is protected, i.e. define "plant variety".

¹⁸ 1997, p 26

¹⁹ Leskien & Flitner, 1997, pp 26-32.

Some WTO Members argue that plant varieties are not subject to the national and MFN treatment because they are not IPRs for the purposes listed in the footnote to Articles 3 and 4 of the TRIPS Agreement.

Distinctness - clearly distinguishable in one or more important characteristics from any other plant variety.

Uniformity - sufficiently uniform in its relevant characteristics with variation as limited as necessary to permit accurate description and assessment of distinctness and to ensure stability.

Stability - the relevant characteristics remain unchanged after repeated propagation.

2. The conditions under which protection is granted, i.e. if it meets the requirements of novelty or inventiveness as under patent legislation, or distinctness, uniformity and stability (DUS) as under PBR legislation, or some modified version of these to protect more heterogeneous varieties. Whether to include additional requirements like 'Declaration of Origin' and 'Value for Cultivation and Use'.
3. The scope of the rights conferred, i.e.
 - list the acts requiring the right holder's authorisation (selling, producing importing etc.),
 - the definition of materials to which these acts refer (reproductive and/or vegetative propagating material, harvested material etc.), and
 - the exemptions from the right (such as research exemption, breeders' exemption and farmers' exemption).
4. The time for which the right exists, i.e. the number of years the right lasts. This could be any economically relevant period of time.

The International Plant Genetic Resources Institute (IPGRI), in producing a checklist for use in developing a *sui generis* system argues that an IPR suitable for an industrialised system of production geared towards export is unlikely to be suitable or appropriate for an agricultural sector characterised primarily by subsistence farming²⁰. Since both systems may exist in the same country they suggest it may be worthwhile for countries to explore how options can be mixed and matched, including the prohibition of double protection and providing different levels of protection for varieties of the same species depending upon their intended use. What is appropriate depends upon:

- the type of domestic seed industry that exists;
- the level of use of farm saved seed;

²⁰ IPGRI, 1999

5. UPOV and PBRs – a critique

Genetic Resources Action International (GRAIN) and other critics argue that the criteria used for "protection" - that varieties are distinct, uniform and stable - lead to genetic erosion. Its most widespread cause, according to FAO, is the replacement of genetically diverse and locally adapted seeds by genetically uniform modern varieties.*

The UPOV system promotes commercially bred varieties geared for industrial agricultural systems in which farmers have to pay royalties on such seed and the seed sector becomes an investment opportunity for chemical and biotech concerns. These breed plants to grow successfully with their proprietary chemical inputs or with their patented genes at the expense of more sustainable biodiverse systems, argues GRAIN.

Since PBRs are only given for a variety that is genetically uniform they automatically limit both what kind of seeds can be marketed and who can market them and so UPOV automatically discourages genetically diverse and locally adapted seeds from the market and from the field, say its critics.

GRAIN rejects seed industry claims that plant variety protection through PBRs has increased R&D. They quote

an impact study in the USA, for example, that found that 'the *prima facie* evidence suggests that the PVP has had a positive effect on private plant breeding R&D for a few specific crops,' mainly wheat and soybean. There was no net positive effect for the public sector, which has a broader agenda than that of industry. In fact, GRAIN argues that the public sector has been pushed out of applied research toward a basic research agenda for the benefit of corporations. They say that countries need more appropriate incentives for sustainable, diversified farming systems that safeguard the rights of local communities and not UPOV or PVP, in particular because under the UPOV 1991 rules:

A breeder may have some rights in relation to the harvest: If farmers sowed their fields to a PVP variety using purchased seed on which the royalty had not been paid, the breeder could sue the farmer for infringement of his rights. The breeder has no rights in relation to the harvest when a farmer resows his own seed exercising the farmer's privilege but UPOV 91 Art 13(2) shows that the breeder has rights to the farmer's actual harvest (plants, plant products) in certain cases.

Further breeding is restricted: Anyone using a PVP variety in creative research has to make significant changes to the genotype or else the 'new' variety will not be considered as 'new' but as an 'essentially derived' variety which cannot be exploited without the permission of the first breeder.

Farmers cannot freely save seeds for their own use: The 1991 Convention does not require countries to protect the rights of farmers (so-called 'farmers' privilege') to freely use their harvest as further planting material. However, it expressly allows countries to permit seed saving by farmers and, in practice, virtually all countries make special provision for the right to reuse seed in their national laws although this is usually restricted to individual farmers working on their own private holdings.

Varieties can be patented: The 1991 Convention leaves member states free to decide whether varieties can be patented but all existing member States which are party to the 1978 Act remain bound by the ban on double protection in that Act.

*FAO, 1996

Source: Gaia Foundation/GRAIN, "Ten reasons why not to join UPOV"

6. The Philippines' system

A new Intellectual Property Code in the Philippines, adopted to conform with TRIPS, came into effect in January 1998. Under the code, plant varieties and animal breeds or essentially biological process for the production of plants and animals are excluded from patent protection but not micro-organisms and non-biological and microbiological processes. It also includes provisions for Congress to enact a law "providing *sui generis* protection of plant varieties and animal breeds and a system of community intellectual rights."

A draft PVP proposal before Congress mixes elements from UPOV type legislation, mostly the 1978 Convention, with national requirements including Environmental Impact Assessments. These cover socio-economic concerns, genetic erosion; genetically modified organisms; a fund to promote community conservation; and special treatment

of traditional property regimes when these imply collective rights. It provides protection to all cultivated varieties of all botanical genera and species, including hybrids between genera and species satisfying the Distinctness, Uniformity and Stability criteria. It does not apply to varieties which have been in use by a farmer or indigenous communities for at least a year prior to the date of application. Indigenous cultural communities may apply for a Certificate of PVP and to be represented by a traditional leader or person/s chosen by the majority. It reserves power to the President to prohibit the use or entry of any new variety for conservation, biosafety or public safety reasons. The protection provided does not extend to seeds saved from a protected variety or acts done for experimenting, breeding, discovering and developing other varieties.

This IPR legislation is seen as comple-

mentary to other legislation such as that on community rights related to biodiversity (plants and plant varieties). The Indigenous Peoples' Rights Act (IPRA) and the Traditional and Alternative Medicines Act (TAMA) were both adopted late 1997 and also provide for community intellectual rights over biodiversity and local knowledge. The emerging *sui generis* system in the Philippines, then, would consist of adapted PVP plus community intellectual rights, each partly dependent upon the legitimacy of the other. Throughout, this emerging regime stresses the need to conserve the country's biological diversity as a national priority.

Note: Copies of the above and other legislative texts establishing new rights regimes over biodiversity in developing countries are available by email from <grain@baylink.mozcom.com>.

Source: GRAIN (eds), 1998

- the current capacity of breeders;
- local (national) breeders' aims in the next 5-10 years;
- the country's biotechnology capacity;
- the goals and realistic expectation of the biotechnology sector; and,
- the types of strategic alliances likely to be entered into.

IPGRI also stresses the need, whatever IPRs are used, for appropriate mechanisms to prevent any monopolist effects of IPRs particularly patents. These include:

- anti-trust laws;
- shifting the burden of proof in the 'enablement entitlement' in patent law, i.e. so patent claimants have to prove wide-ranging claims will work rather than the challengers that they will not;
- rigorously applying the inventive step and industrial application requirements;
- mechanisms to balance the claims of initial and subsequent innovators; and,
- limiting or prohibiting the use of functional claims.

2.2.4 The combination option

A mixed system of patents and a *sui generis* system of PVP provides the strongest IPRs regime as this allows both types of IPRs to be used. It is of the most advantage to industrialised countries with active seed breeding and biotechnology industries. Use of patents is more likely to encourage consolidation in the seed industry because they are expensive. Europe, which tends to prefer PVP, has many small and medium sized seed businesses. It is unclear if this option means any object must be covered by both patents and PVP or that every object must be covered by either PVP or patents and perhaps by both.

2.3 Fiscal, legal and market implications

Taking a full and active part in the emerging global IPRs system involves a number of transaction costs. These include the costs involved in developing the appropriate laws and enforcement mechanisms within each country. Patent examiners need special training to deal with biotechnological applications and, for PVP, an appropriate administrative system must be established. WIPO operates training schemes for developing countries and provides assistance to those seeking to implement the TRIPS Agreement and use UPOV.

7. US litigation experience

US experience so far in plant biotechnology litigation shows two main types of dispute. One, as expected, concerns disputes over use of a particular gene sequence or the like where patent rights would provide the exclusivity that would be an incentive for research. This leads to different seed companies assembling licenses

to create competing combinations of novel genes and traditionally-bred ones in new plant varieties.

The other, however, "is essentially the use of patents that cover an entire market in an apparent effort to drive all competitors out of the market (or at least create a strong negotiating position for a licensing agreement)" says

John Barton. There seem to be "so many such broad and fundamental patents that, in essence, every major actor may be violating a patent held by every other major actor," he says. This will be a global issue but it is presently being fought out in the US courts.

Source: Barton (1998)

These transaction costs may only be partially born by governments, however. Patent and trademark offices can be self-sufficient operations through the levies from application and renewal fees. A careful balance has to be struck, however, between generating revenues for the administrative office and keeping fees sufficiently low not to exclude small-scale inventors from the IPRs system.

Obtaining a patent can be quite expensive. Preparing a US patent application in the early 1990s cost about \$20,000, with one in the EU costing about twice that. PBR's, however, are cheaper - about a tenth the cost of a patent²¹. Patent applicants must apply for patents in every country where they want them, pay an annual fee to maintain the patent and pay patent agents costs. The costs of filing a patent also vary greatly, ranging from \$355 to \$4772 in 32 countries surveyed in the early 1990s²². For firms at the forefront of biotechnology, establishing who has what rights of ownership over new processes and plant varieties is also a costly business as firms engage in litigation to determine who has what rights and to secure their markets (Box 7).

The market structure is also very important in assessing the likely impact of changes in the IPRs regime, and the role different actors can play, according to John Barton of Stanford Law School²³. There is an increasing trend to economic concentration of market power in larger and larger enterprises throughout the developed countries, including in the seed industry²⁴. One argument for mergers is that larger firms will be able to raise capital more easily than the small firms that made up the industry. Another is that there are economies of scale in R&D activities. The existence of an oligopoly also gives the firms greater pricing freedom and so enables them to recover research costs. Such a structure also provides an incentive for small firms to invest in biotech innovation in the expectation that they will recoup their costs and make money when they are sold to the large firms.

There are potential problems, however, and not simply of control over prices. It may produce declining incentives for research. "The incentives for the industry leaders to conduct research are now limited...new smaller firms may now find it impossible to enter the business because they face the assembled patent rights of the industry leaders and possibly also face contract restrictions on access to marketed materials that would once have been available for further breeding", says John Barton.

He sees the key challenge as finding a way to reverse the oligopoly while maintaining the use of IP incentives to encourage research. These might include a tougher application of the non-obviousness principle, restricting the scope of patent claims by making claimants prove the applicability over broad areas, and creating strong experimental use exemptions.

²¹ Lesser, p 12-13

²² Helfgott, 1993

²³ Barton, 1998

²⁴ Tansey and Worsley, 1995

3. Issues for the review of Article 27.3(b)

3.1 Timetable

The Council for TRIPS will review Article 27.3(b) in 1999. At its meeting in December 1998, there was an initial exchange of views about how to carry out the review. As a first step, it was agreed that an information gathering exercise would be carried out and that relevant organisations such as the FAO, the Convention on Biological Diversity (CBD) and UPOV would be invited to provide information on their activities of relevance to the Council for TRIPS. It was understood that this information gathering exercise would be without prejudice to the nature of the review.

“Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”.

Article 7, TRIPS Agreement

3.2 Scope

The provisions of Article 27.3(b) were hotly contested in the original GATT negotiations and there is no consensus about what the scope of the review should be. Some, mainly developed countries, see it as a review of the extent to which the provisions have been implemented. Others, mainly developing countries, see it as a review of the provisions themselves that could lead to revision of the text.

The review is taking place before most developing countries have had to comply with the provisions, and before there has been much analysis or evidence of their effects in those that do. The alternatives range from a narrow legalistic review of implementation and definition of terms to a broad assessment of how far the provisions go towards achieving the broad goals of the TRIPS Agreement. The broader the scope, the more time it is likely to take. Some countries fear that an information gathering exercise, especially if narrowly focussed on implementation and extended to countries which do not need to comply until 2000, will provide the ammunition needed for other countries to take them to the disputes settlement procedure as soon as the 2000 deadline passes.

3.3 Review options

Patrick Mulvany suggests five options for the review²⁵:

1. A rapid completion of the review, possibly by agreeing that no changes to the text are required.
2. Seeking to delay the review and the legislative timetable until after the full TRIPS review due in 2000 has been completed.
3. Opening the review, as required, but then completing it in parallel with the full TRIPS review and the renegotiation of the Agreement on Agriculture over subsequent years.
4. Examining possible conflicts between some Members' obligations under the CBD (Box 8) and those under TRIPS, in the WTO's Committee on Trade and Environment (CTE) before the review can be concluded. However, the existence of any such conflict is highly controversial.
5. Requiring satisfactory completion of the negotiation of the revision of the International Undertaking on Plant Genetic Resources (IU) and assessing what its implications are before completing the review (Box 9).

Options that confine discussion to within the Council for TRIPS and which might lead to amendment of the provisions require agreement by consensus. Those that lead to considerations of amendments alongside negotiations on other issues in the next round of trade negotiations make it more likely that changes could be agreed if countries traded-off a shift in their position on Article 27.3(b) for a concession elsewhere. In this kind of exchange, the most powerful and informed are likely to be best able to benefit.

²⁵ Mulvany, 1998, p 27

8. The Convention on Biological Diversity - CBD

The legally-binding CBD's aims are "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies." (Art 1) By early 1999, some 175 countries were party to the CBD but seven, including the USA, had not ratified it. The Convention:

- Recognises the sovereign rights of states over their biological and genetic resources* (Arts 3 and 15).
- Stipulates that access to genetic resources can only occur on mutually agreed terms and with the 'prior and informed consent' of states, unless states have otherwise determined (Art 15.5) - but these rules do not apply to seed in gene banks collected prior to the date when the CBD came into force. Such *ex situ* collections are dealt

with in the IU.

- Requires signatories to protect and promote the rights of communities, farmers and indigenous peoples *vis-a-vis* their customary use of biological resources and knowledge systems (Arts 8j and 10).
- Requires each Party to endeavour to facilitate access by other Parties for environmentally sound use (Art 15.2)
- Requires transfer to be on terms which recognise and are consistent with the adequate and effective protection of intellectual property rights (Art 16.2) and aims to enable developing countries, which provide genetic resources, to have access to technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights (Art 16.3)
- Requires the equitable sharing of benefits arising from the commercial use of communities' biological

resources and local knowledge (Art 15.7).

- Asserts that intellectual property rights must be supportive of and not run counter to the objectives of the CBD (Art 16.5).

The Conference of the Parties (COP) to the CBD recognised "the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions" (Decision II/15) and supported the re-negotiation of the International Undertaking on Plant Genetic Resources at FAO. Like the TRIPS agreement, there are ambiguous or unclear elements in the CBD which make interpretation difficult.

** Biological resources* includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

Genetic resources means genetic material of actual or potential value.

Source: Gaia Foundation/Grain, "TRIPS versus CBD" and CBD legal texts

3.4 The developed countries' positions

The USA basically favours extending patent protection. Long-term, the USA would be happy to see the clause allowing animals and plants to be exempted from patenting deleted. In the interim it would prefer the *sui generis* option to be written out and UPOV 91 inserted as the only PVP option²⁶. In general, this is the position favoured by pharmaceutical and agri-biotechnology industries. Most other OECD members would also prefer UPOV 91 as the sole *sui generis* option. The EU would probably want to retain the UPOV PVP option for plant varieties, but an EU position on extending patent protection may be difficult to arrive at since the Dutch formally challenged the legitimacy of the EU Patent Directive that allows patents on plants and animals. Some business organisations, such as the International Chamber of Commerce (ICC), fear that any tampering with the existing provisions of the article could lead to a weakening of the IPRs provisions²⁷.

3.5 The developing countries' positions

The developing countries have a wide range of interests depending on factors such as:

- whether they are net food importers or exporters;
- how extensive their biodiversity is;
- the nature of their farming economy;
- the degree of industrialisation; and,
- whether they have an established biotech industry or not.

Their positions may also be influenced by the degree of pressure they come under from other countries and what they think they can gain in future trade-offs should decisions on revising the provisions extend into a new round of negotiations. Although the least developed countries do not have to implement this article until 2005, any decisions taken now could affect what they have to do.

In general, developing countries wish at least to keep their options open and have more time to examine the issues and possibilities. This would mean a minimum position of no change to the existing text. If the text is to be revised, some civil society groups and governments would prefer animals and plants to be excluded from

²⁶ Lourie, 1998

²⁷ *Inside US Trade*, 30 Oct 98 and ICC paper 450/869

patentability and the requirement for a *sui generis* system of protection of plant varieties to be removed²⁸. Individual countries, especially the least developed, could request more time to implement their commitments. This may be the only realistic option given the short time remaining for implementation and lack of capacity in many countries to develop a *sui generis* system. It would also provide time to learn from those Members working on *sui generis* systems. They may also seek clarification of terms. Some authors are suggesting the types of definitions and actions concerning the provisions that developing countries should take (Box 10), while others are discussing various elements of possible *sui generis* systems (Box 11).

3.6 National policy coherence

Considerable work is needed to prepare a national position for the review, argues Patrick Mulvany. He suggests actions at various levels:

1. Locally within communities, a rapid assessment of the potential implications of different options:
 - on the conservation and sustainable use of natural resources;
 - on local production from plants and animals;
 - on local communities and producers and their collective knowledge systems; and
 - on local biologically-based industries.
2. Nationally, a rapid survey of the work by different ministries and agencies on TRIPS and all related international agreements on the ownership, conservation and sustainable use of plants, animals and biological processes. Inter-ministerial working groups, or similar bodies, should address all aspects of these issues and ensure national policy coherence. They should also address the legal implications and costs of different courses of action.

“Any region of the world is dependent on genetic material which originated in other regions for over 50% of its basic food production, and, for several regions of the world, such dependency is close to 100%.”

FAO, Sept 1998

²⁸ Gaia, Nov 1998

9. The International Undertaking on Plant Genetic Resources – IU

The negotiations to revise the International Undertaking on Plant Genetic Resources for Food and Agriculture in harmony with the CBD started in 1994, in the inter-governmental FAO Commission on Genetic Resources for Food and Agriculture (CGRFA), of which 159 governments and the EC are members. Countries are agreed on the need for a multilateral framework to facilitate access to plant genetic resources of the main crops, for which countries are highly inter-dependent, and which are important for food security, and benefit-sharing, to enable future progress in plant breeding. In these cases, a bilateral system could hinder the flow of germplasm needed for breeding.

The negotiations concern the scope of the Undertaking, the rules governing access to genetic resources for food and agriculture, benefit sharing and the realisation of Farmers' Rights*. By the end of 1998 it had been agreed that the scope of the IU will be all plant genetic resources for food and agriculture (PGRFA), managed under a system of facilitated access to PGRFA. The mechanisms for this, including a possible multilateral international fund

or other financial arrangements for benefit sharing, are currently being negotiated.

The issue of ownership rights over the *ex situ* collections of plant genetic resources made before the entry into force of the CBD, which mainly originated in developing countries and are widely used in plant breeding, is also being considered. The IU currently provides an umbrella, through the International Network of *Ex Situ* Collections under the Auspices of FAO, into which 12 International Centres of the Consultative Group on International Agricultural Research brought their collections in 1994, and under which they hold their material in trust (see Box 12).

The proposed multilateral system of access to PGRFA, and the open exchange of breeding material within it, without any controls, but with a multilateral benefit-sharing mechanism, is likely to have substantially lower transaction costs than attempting to track every change in a plant variety, allocate values to each and then distribute some part of them to different contributors.

The debate about Farmers' Rights, has

focused on:

- recognition of their role in developing and breeding the basic genetic material used in plant breeding.
- support for their role in conservation and sustainable development (such as through research services); and
- how farmers, especially small farmers, share fairly in any benefits flowing from the enhanced use of their genetic resources. The next negotiating session is expected to be in April 1999.
- farmers', particularly small farmers', right to sow seeds from crops they have grown (often known as 'Farmers' Privilege');
- their participation in decision-making about agricultural development

**"Farmers' Rights mean rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in the centres of origin/diversity. These rights are vested in the International Community, as trustees for present and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuations of their contributions, as well as the attainment of the overall purposes of the International Undertaking."*

Source: FAO Conference Resolution 5/89 - Twenty-fifth Session of the FAO Conference, Rome, 11-29 September 1989

10. An Indian view of the provisions

Bhagirath Lal Das, a former Indian Ambassador to GATT, believes the meaning of various provisions in Article 27.3(b) relating to plants and animals needs clarifying to avoid firms gaining advantages that damage developing countries' interests. Acknowledging his debt to work done by Prof Correa, he suggests countries:

1. State that naturally occurring plants, animals, the parts of plants and animals including the gene sequence and essentially biological processes for the production of plants, animals and their parts, must not be granted patents.
2. Define the term 'micro-organisms' to refer to genetically altered micro-organisms and not to naturally occurring micro-organisms, e.g. naturally occurring bacteria, fungi, algae, protozoa or viruses.
3. Not grant patents to a subject mat-

ter which was available to the public by means of use, written description or in any other manner in any country - or which have been in use by local and indigenous communities - prior to the date of filing of the application for patents.

4. Forbid the patenting of plant materials obtained from collections held in international germplasm banks and other deposit institutions where such materials are publicly available, and if such patents have been granted, these should be cancelled.
5. Agree that patents must not be granted in such cases without the prior consent of the country of origin and that patents inconsistent with Article 15 of the CBD must not be granted.
6. Agree that if the subject matter of a patent is derived from the bio-resources of a country, it should be

obligatory on the patent holder to share economic benefits from use of the patents with the country of origin and also with the indigenous communities that have nurtured the bio-resources for a long time.

7. Where patents are granted to allow free use of the subject matter for scientific experimental use and breeding.
8. Agree that a country is free to choose its own *sui generis* system for the protection of plant varieties, and to itself decide what is an effective system. The test of effectiveness should not be the subject of multilateral examination.
9. In general, it should also be agreed that unilateral retaliatory action should be explicitly and clearly prohibited.

Source: Das, 1998

3. Regionally, within country-blocs, a comparison between the needs, specific circumstances and obligations of different countries to identify stronger negotiating positions in the review and related negotiations²⁹.

He suggests inter-ministerial working groups, or similar bodies, should address all aspects of these issues and ensure national policy coherence since the TRIPS Agreement is one of several international obligations affecting the ownership and control of plants and animals. The three others most closely connected are:

- negotiations on the implementation of the CBD, including on the adoption of the Biosafety Protocol ;
- negotiations in the Food and Agriculture Organisation of the United Nations (FAO) on the revision of the IU which may become a protocol to the CBD; and,
- actions to implement the Global Plan of Action on Plant genetic Resources for Food and Agriculture that was agreed by governments in Leipzig in 1996.

The negotiations in the CBD and on the IU and any on Article 27.3(b) need to be "complementary and mutually supportive", in particular in providing for access and benefits sharing and in ensuring that different IPRs regimes do not conflict or that reactions to one, such as patents, result in restrictions in another, such as access to genetic resources³⁰. Those at the IU will be particularly important for use of the materials held in various gene banks which were collected before the CBD came into force (Box 12).

Trade ministries usually deal with the WTO. IPRs may be the responsibility of a Patent Office, usually in a Trade or Industry Ministry, or, in the case of seeds, a Plant Variety Office, usually in a Ministry of Agriculture. Environment is often handled by a separate ministry or agency while Agricultural Ministries are usually responsible for negotiations on genetic resources for food and agriculture. Each of these ministries may be advised by formal bodies, often research councils or institutions, in which the detailed analysis is done. This separation of functions among different ministries and agencies can lead to a loss of policy coherence and weaken a country's position if there is a lack of collaboration and coordination between ministries and agencies.

Policy coherence ensures a balanced decision-making process, taking account of wider impacts on parallel ministries and the sectors for which they are responsible. It should also lead to more effective participation in negotiations and more informed trade-offs. Policy coherence developed in capitals across these areas should also extend to negotiators in Geneva and elsewhere. This need for policy coherence applies across the board in developed as well as developing countries.

²⁹Mulvany, 1998, p 30

³⁰FAO, Sept 1998

3.7 Legal interpretations and dispute settlement

The WTO Agreements are legal texts in which the language is open to interpretation and different parties will interpret it in different ways. Both the Ministerial Conference and General Council of the WTO have the authority to interpret the TRIPS Agreement. Decisions are made not by voting but by consensus, continuing GATT's tradition, although the WTO Agreement does allow for voting³¹. Disputes over interpretation are subject to rulings by the WTO dispute panels and, ultimately, the Appellate Body, against which there is no appeal. Anyone then found to be in breach of the rules, as so interpreted, will have to amend their rules or face sanctions. If sanctions in the same area covered by the same agreement or in a different area are not feasible then cross-sectoral trade sanctions in areas covered by another WTO Agreement could be imposed.

It is premature to say how any disputes over this clause will be viewed. It is likely, however, that the threat of legal action may deter some governments from following what they believe is an appropriate interpretation of the rules for them but which would leave them open to a costly challenge.

One possibility is to link interpretation of the WTO Agreements with other obligations also entered into by states, notably those in the CBD in Articles 15 and 16. However, this and other obligations are also legal texts open to legal interpretations but lacking the strong legal dispute settlement mechanism of the WTO.

³¹WTO, Feb 1998, p 60

11. Geographical indications

There have been discussions in some developing countries about the possible use of geographical indications as an element in a *sui generis* system, perhaps for farming-community based varieties. Geographical indications are, as Article 22 of the TRIPS Agreement defines them: "indications which identify a good as originating in the territo-

ry of a member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin". They are designed to give consumers confidence that the products they buy come from a specific place and are already widely used for some products

like wines. They might be important for products of plant varieties or animals breeds that already have or may gain a favourable international or national reputation. However, since they generally apply to products it is not clear how their use would fit into a *sui generis* system of plant variety protection.

12. Gene banks

Over 1300 gene banks hold over six million accessions, largely as a result of the wide degree of access to plant genetic resources for food and agriculture historically. Many of the largest gene banks in the world, including those in Europe, North America, and in the Consultative Group on International Agricultural Research (CGIAR) system have policies of unrestricted availability to *bona fide* users

as do some gene banks in developing countries, though scarce resources for multiplication and processing may limit or delay availability. The material in the largely publicly-funded CGIAR system is still held in trust for humankind by FAO, following an agreement in 1994, to be used to support research of benefit to developing countries. Despite this agreement there have been several instances of

material from the CGIAR system finding its way to commercial breeders in industrialised countries who have tried to patent it. In mid-1998, the chairman of the CGIAR called for an immediate halt to the granting of any form of plant breeders' rights or any other form of IPRs on the varieties held by the CGIAR's International Agricultural Research Centres.

4. The wider issues – ethical, economic, environmental and social

The implications of this small clause of the TRIPS Agreement, itself a major shift in international law covering many areas, should be seen in a larger context. The following four sets of issues are not exhaustive but illustrate the range of concerns involved: moral and ethical, economic, environmental, and social. In each set we have focused only on some of the principal concerns.

4.1 Moral and ethical concerns

Moral and ethical concerns arise over the extension of patents to lifeforms and over the way in which agreements are arrived at. They fall under a number of headings:

“Fundamentally, the question is whether civic democracy is compatible with global deregulation, and whether the WTO’s intellectual property rights’ for biotechnology discoveries will take us all into an era of corporate feudalism.”

Alan Simpson, MP, 1999

“By requiring all parties to the agreement to eventually meet high standards for protecting intellectual property, TRIPs has as an overriding goal to stimulate and foster human creativity for social progress”

Gerald J Mossinghoff, a former US Commissioner of Patents and Trademarks, and an ex-Chairman of the General Assembly of WIPO, 1998

4.1.1 Invention - human or divine?

Many religious and cultural traditions regard the extension of patents to living organisms as intrinsically wrong. In particular, the claim to human invention in relation to living material violates the belief in a divine creator and that life is a gift – the shared inheritance of human kind. Patenting of lifeforms “marks a significant further step in the larger process of the commodification of life” and the “reduction of the value of life and nature to the merely economic”³². In particular, many groups worldwide are concerned that patents underpin developments in genetic engineering that risk disturbing a complex pattern of inter-relationships in the natural world that we still only partially understand.

4.1.2 The living world - shared inheritance or private property?

Many opponents of patenting on lifeforms see this as an inappropriate extension of private ownership rights to resources that should be or were previously held in common. Western IP regimes, as an extension of an individualistic culture, generally make no allowances for the protection of communal rights and intergenerational innovation which are the hallmark of many developing country cultural traditions. Some countries, for example, Australia and Canada, have developed existing IPRs legislation to protect indigenous communities’ knowledge and WIPO is looking into this³³.

4.1.3 The balance of interests

Patent law represents the balance that society has struck between the principle of rewarding inventiveness in a competitive commercial culture and the principle of knowledge gained from research being freely available. However as a result of increasing privatisation, scientific research seems to be shifting away from its traditional values of openness and discussion towards confidentiality and secrecy. As a result, there are concerns that with the growing power of the corporate sector, the extension of patents to lifeforms will tip an already unequal balance and strengthen the power of corporate interests while further marginalising questions of human welfare and social justice. Some groups advocate a complete rethink of the way innovation is promoted in agriculture and the life sciences.

4.1.4 Democratic deficit - need for a framework of ethical assessment

Donald Bruce in *Engineering Genesis* points to a growing democratic deficit that is developing in our increasingly globalised society where momentous decisions which could alter the whole future course of humanity are taken in fora which are outside

³² Bruce, 1998, pp 229 and 231

³³ WIPO, 1998

democratic control. Commercial experts and NGO activists alike are not effectively accountable to anyone. He points to the need for three things essential to keeping democracy alive:

- to “develop a political culture in which politicians are educated to appreciate the scientific and ethical issues involved as well as, say, the political and commercial aspects”;
- for public education which can make the difference between elite pluralism and democratic pluralism; and,
- for the media “in developing critiques of what powerful interests are engaged in”³⁴.

4.1.5 Equity in international negotiations.

A fair and equitable negotiating process is desirable for the long-term success of international trade agreements. Further, the legitimacy of any rule-based system depends on it being equally accessible to all members. At present the difference in resources and capacities between the negotiating parties is so great that many observers feel that all WTO Members could hardly be said to be equally able to participate in negotiations or to take equal advantage of the WTO dispute settlement procedure. In such circumstances, any final agreements are unlikely to represent a fair balance of interests. Much still remains to be done to produce a balanced negotiating system which is not unduly dominated by a few powerful countries which are themselves heavily influenced by the corporate sector.

4.2 Economic issues

There is considerable debate about the economic impact of IPRs in general and determining the benefits and costs related to changes catalysed by new IPRs regimes is a complex economic problem. Two areas are of particular concern given the objectives of the TRIPS Agreement - technology transfer and R&D in the agricultural sector.

4.2.1 Technology transfer

There is little empirical evidence about the impact of patents and PVPs on agricultural investment or on their effects in developing countries on the rate of technology transfer to them or on the stimulation of local R&D³⁵. The International Food Policy Research Institute (IFPRI) plans, funding permitting, to examine the economics of IPRs and implications for the use/transfer/access to agricultural genetic resources. The project includes case studies and a pilot study of the experience with the US patent acts, for example, on wheat varietal change and its effects.

The effects of patents on technology transfer are disputed. One view is that they assist the technology transfer process in two ways:

1. The published patent title discloses information to the benefit of other researchers.
2. The ability to retain control over their technologies allows companies to transfer complementary skills to other countries - either through licensing agreements or through foreign direct investment.

Another view, however, is that:

1. They may nowadays restrict the free flow of new knowledge and scientific information and so inhibit scientific creativity and technological change through imitation.
2. If importation fulfils working requirements related to IPRs, as foreseen by TRIPS, companies may be less inclined to transfer their skills to other countries. Although Article 31 of the TRIPS Agreement permits compulsory licensing agreements, legal interpretations differ over the extent to which compulsory licenses can be used for technology transfer purposes.

One concern about patents is their effects on the flow of breeding materials - animals and plant germplasm. To date, since farm animals are mostly not covered by patents, the focus has been on plants. There is evidence that the strengthening of IPRs is leading to restrictions on the flow of germplasm (breeding materials) and so

“IPRs, perhaps uniquely among business regulations, can both support and limit competition”

Maskus, 1998, p 147

“the Western, industrial model of innovation is...antithetical to the ethical and social values and needs of many Third World Countries and peoples. It is critical, therefore, to redefine ‘innovation’ in a manner which is protective of the creativity of indigenous peoples.

Gurdial Singh Nijar, 1996, p 26

³⁴ Bruce, 1998, pp 270 and 271
³⁵ van Wijk et al, 1993

inhibiting the development of new plant varieties, particularly by the publicly-funded institutions such as those supported internationally by the CGIAR. The seed industry itself is concerned about the reduced flow of germplasm and recognises the need to ensure this flow is maintained³⁶.

This issue is linked to measures to control access to these materials as envisaged in the CBD. It is also linked to concerns that biodiversity is maintained since it is the source of future breeding materials for human uses. Another concern is whether and how those who have developed genetic resources through many different traditional, communal systems should have control over access to this material and receive benefits from its use in products that subsequently are marketed.

“The emergence of biotechnology has enabled chemical companies to expand their research base to include plant genetics, thus facilitating their entry into seed production. The chemical industry traditionally relied on the patent system and has therefore become a strong advocate of patent protection for plant material.”

van Wijk et al, 1993 p 11

4.2.2 R&D priorities

The importance of patents and PVP is increasing in part due to changes in the funding of R&D for agriculture. Until relatively recently agricultural R&D was largely publicly funded. Research results were given to farmers through extension services in the hope they would adopt new methods to increase their productivity.

The financial returns for publicly financed R&D into improved farming productivity are high for both developing and developed countries. The US economy, for example, benefited from its investment of \$134 million worth of support to international wheat and rice research aimed at developing countries by up to \$14.7 billion³⁷. In the OECD countries private spending now accounts for about half of R&D. In many cases governments have moved away from near-market research, which has immediate applicability on farms, to focus spending on basic research which underpins future private R&D efforts. In some countries resources have shifted into areas supporting agribusiness and food processing which “may have reduced rather than increased the rate of return to public sector research” according to Alston, Pardey and Smith³⁸.

The private sector, naturally, invests in areas where it can hope for a return - with much work in agrochemicals over the years. Today, former agrochemical companies have expanded to become biotechnology/seed companies (or life science companies including pharmaceuticals) moving downstream to add value to their products. Huge investments have gone into this area - over \$8 billion per year in the USA alone, according to Ismail Serageldin, Chairman of the CGIAR. He is concerned that this private proprietary science will focus on crops and innovations that will find rich markets and ignore those of interest to poor, small farmers³⁹.

Hans Herren, Director General of the International Centre of Insect Physiology and Ecology in Kenya fears “the trend towards a quasi monopolization of funding in agricultural development into a narrow set of technologies is dangerous and irresponsible”. He argues that the new ‘miracle’ technologies are not needed to solve the food security problem and is concerned that the focus on biotechnology R&D and developing what are essential copy-protected, branded solutions to problems - linked to IPRs - is far too narrow an approach to agricultural development⁴⁰. He believes it will lead to a narrowing of the range of solutions explored to solve problems - especially solutions that can be freely adopted, adapted and exchanged by small farmers.

How far stronger IPRs in low-income developing countries would stimulate local research focusing on the needs of domestic farmers is unclear. Large developing countries such as India, for example, have a large pool of qualified scientists, which could form their own research-based agricultural enterprises once they are assured their research outputs are protected.

Stronger IPRs may also open the door to new types of research alliances. Driven by the biotechnology revolution, researchers from developed countries increasingly rely on starting materials taken out of the bio-rich developing world. Although this raises concerns of adequate compensation for developing countries, such research could benefit both developed and developing countries with initial screening of biological material performed by developing country enterprises collaborating with large Western research-based agrochemical companies.

³⁶ FAO, Sept 1998

³⁷ Pardey et al, 1996

³⁸ Alston et al, 1998

³⁹ *Newsweek*, August 24, 1998

⁴⁰ Herren, 1998

4.3 Environmental effects of patenting genetically-engineered agricultural products

There is a wide range of differing views from within the scientific community and general public about the wisdom of the rapid, widespread adoption of genetically engineered organisms in the food system. In so far as the TRIPS Agreement is seen to promote that - and patents are essential for the industries involved - there will be a link made between them. This is not the place for discussion of the different viewpoints and scientific arguments about biotechnology. The issues raised by patenting concern the level of responsibilities and liabilities patent holders and licensees will have for any adverse consequences of the application of the inventions for the environment and human well-being. These may cross over into other fields of law - such as corporate governance and limited liability.

Also since patenting, in the context of the rapid development of genetic engineering, is linked to introduction of genetically-engineered plants, it can be argued that a country needs first to establish appropriate biosafety rules and control systems before considering the enactment of patent regimes that could encourage the development and release of these plants. The Biosafety Protocol of the CBD is due to be completed in February 1999. It should provide the international framework for these systems although many NGOs fear a weak framework will be agreed owing to heavy pressure from industry lobbying.

4.4 Social effects on farming systems

PVP regimes were developed for commercial breeders serving commercial farmers in the industrialised countries where farmers are a small percentage of the population, farming is commercial, seeds are bought from commercial suppliers, and products are commodities which are exchanged via markets. In many developing countries, these conditions only apply to a part of the domestic-focused agricultural sector and to the main export crops. Many farmers are in local communities with a domestic, local market focus and often practice a large measure of subsistence farming. The farmers are more numerous, many crops are local food crops which are not widely traded and varieties used are local with much seed saved from year to year and exchanged among farmers in the community. The crops grown are often not uniform commercial varieties but farmers' varieties (landraces) which have a wide range of genetic characteristics and assure a food supply by ensuring at least some yield even in difficult conditions.

If patents and PVP contribute to R&D focused on the needs of small farmers, of locally important food crops and produce low cost solutions amenable to them then they could have a very favourable impact on local farming systems - helping improve their productivity without producing massive structural change.

There are fears, however, that patents and PVP will facilitate the commercialisation of farming along the lines of farming systems in the industrialised countries and so rapidly undermine the whole base of small-scale mixed subsistence and local market based production systems. If R&D produces varieties and methods most suitable for medium- and large-scale farmers, rather than products and methods geared to small farmer needs, many small farmers will be squeezed out. Such a result would probably greatly increase population movements to urban centres.

For most small-scale farmers access to land and water, seeds and tools are the basis of their food security. For many, complete dependence on the market for their inputs or to buy their food needs is simply too risky and is likely to be so for the foreseeable future. Any new technical opportunities have to be seen within the broader socio-cultural context which will affect whether or not they present real possibilities for the poorest.

"...to provide any kind of 'protection' of rights is to bring indigenous peoples and local communities and their resources into the fold of the market economy, which with its subversive influences of materialism and consumerism, could overwhelm and ultimately destroy these societies.

The second is to formulate a rights regime which reflects the culture and value-system of these communities as a device to prevent the usurpation, commoditisation and privatisation of their knowledge and ward off any threats to the integrity of these societies."

Gurdial Singh Nijar, 1996, p 24

5. Official Development Assistance

“In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members.”

Article 67, TRIPS Agreement

The public in most developed countries generally support aid to eliminate poverty and hunger. How the current far-reaching technological changes in the agricultural sector and in the legal framework within which food is grown and traded will interact and how they will contribute to human well-being are far from clear. The donor community could play an important role in helping to ensure that any global IPRs regime works to help eliminate poverty.

5.1 Short-term issues for the review of Article 27.3(b)

Donors could consider:

1. Contributing to a more balanced negotiating process by supporting capacity building in countries, across ministries and amongst the various stakeholders, to enable adequate preparation for negotiations and development and support of negotiating positions (see 3.6 above)
2. Ensuring, perhaps through the WTO/WIPO assistance programmes, that sufficient is done to assist in publicly accountable national policy formulation by, for example:
 - providing practical assistance to support electronic contact (phone, fax/e-mail) between Geneva negotiators and capitals - with a minimum basic provision for all countries including Internet access;
 - supporting work on developing *sui generis* systems, including of a form other than UPOV; and,
 - providing assistance to ensure inter-ministerial working on the cross cutting issues between WTO/CBD and the IU.
3. Supporting national capacities to monitor and evaluate implementation of the provisions and to defend national interests in dispute settlement procedures.
4. Supporting development of an international institution offering legal technical assistance in Geneva to assist developing countries in dealing with both the complexities of WTO negotiations and in use of the dispute settlement procedure.

5.2 Longer-term issues for ODA

Current developments raise the questions of how far ODA should do more to:

1. Support multi- and interdisciplinary studies to assess the current status and possible impact of IPRs on food, farming and agricultural biodiversity and their effects on R&D for poor farmers and on poverty alleviation.
2. Encourage and support state funded R&D with poor small farmers on a range of non-proprietary, locally-adapted types of farming technologies and low cost community and area-wide approaches that offer alternatives to the genetically-engineered, copy-protected solutions being developed by the corporate sector in the industrialised countries.
3. Assist countries to develop:
 - the various testing, monitoring, certification, biosafety requirements needed to support adoption of new technologies and legal requirements;
 - the negotiating skills needed to deal with access and IPRs (e.g. material transfer agreements); and,
 - the necessary anti-trust regulations.
4. Encourage and support greater involvement of national and local stakeholder groups to understand, develop and defend their rights.
5. Support research into problems surrounding subsistence food crops.

6. Conclusion

“Because of the complexities in the economics of intellectual property rights, there are no simple rules for regulation”

Maskus, 1998

Article 27.3(b) of the TRIPS Agreement could undermine food security and biodiversity or enhance it depending upon the relative effects of the various provisions. Whatever the costs and benefits of a new IP regime they are not clear cut nor are they likely to be equally distributed.

Logically, it would be better to evaluate the experience of those implementing it in different ways, before reviewing its provisions. These could then be examined in the light of the aims of the WTO agreements and related international commitments. Then their continued relevance and possible modifications could be considered. Until then, and given the many uncertainties on the effect of patents and PVP on agriculture and biodiversity, eliminating the flexibility provided for in the Article seems premature and keeping options open looks highly desirable for most countries. These include: legal options over IPRs and community rights; cultural options, in maintaining belief systems that differ from the dominant one expressed in TRIPS; and technological options that provide a range of solutions to the problems faced by farmers in developing countries.

A trend towards stronger IPRs regimes coupled with the switch to private funding of R&D is changing the nature of research. Public policy and public funding of R&D, along with the national legislative framework within which it functions, should contribute towards the elimination of poverty, the enhancement of food security and the conservation of biological diversity. One way to do so is to support applied research and rights regimes that provide solutions to the problems faced by small farmers. In principle, the products of such research could create a more competitive marketplace giving alternative solutions to farmers to the copy-protected, biotechnology-based products being developed rapidly by the private sector.

In the short term, the immediate actions outlined in section 5 would help improve the quality of the review of Article 27.3 (b). In particular:

- building policy capacity in Geneva and national capitals;
- promoting stakeholder dialogue in developing countries (Box 13) and between country trade missions based in Europe and national capitals;
- setting up inter-ministerial policy groups to ensure policy coherence across CBD, TRIPS and FAO IU negotiations;
- making a broad range of documents and model legislation widely available;
- holding national, sub-regional and regional workshops to promote discussion of the issues; and,
- providing NGO/IGO technical support with information materials on the TRIPS negotiations.

Given the potential impact of patents and PVP on our food future, and concerns over a food system where economic concentration of power is proceeding rapidly, a full and wide-ranging debate is needed to develop policies to produce future food security in a global system that serves everyone.

13. Stakeholder consultations

Consultations with stakeholders are desirable on issues such as:

1. Whose rights are paramount - those of the individual or those of communities? How to balance public and private interests? How to exercise responsibility towards the environment and towards future generations? How to protect collective rights as well as private rights?
2. What national policy to adopt on

patents on lifeforms (plants and animals). If it is *for*, then what is their scope? If it is *against*, whether to prohibit patents on animals and plants now and either develop a *sui generis* system for plant varieties or adopt UPOV or work to remove the requirement for plant variety protection.

3. The relative national importance of community agriculture supported with farmer-saved seed and publicly-financed research compared to com-

mercial farming supported by private seed companies and privately financed R&D. How should the balance be struck? In what direction should the balance change? How fast?

4. How important is biodiversity and appropriate IPRs linked to access/benefit sharing to the country's future development?
5. Is the national position tradeable for concessions in other areas? If so, what for and what guarantees are required?

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Note: e-mail or web site address from which materials may be obtained are given where available. In case of difficulty contact the Quaker United Nations Office in Geneva (see inside front cover for contact details)

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Acronyms

CBD	Convention on Biological Diversity	IU	International Undertaking on Plant Genetic Resources [for food and agriculture]
CGIAR	Consultative Group on International Agricultural Research	MFN	Most Favoured Nation (WTO)
CGRFA	Commission on Genetic Resources for Food and Agriculture (FAO)	NGO	Non-Governmental Organisation
COP	Conference of the Parties (CBD)	ODA	Official Development Assistance
CTE	Committee on Trade and Environment (WTO)	OECD	Organisation for Economic Cooperation and Development
DSB	Dispute Settlement Body (WTO)	PBRs	Plant Breeders' Rights
DUS	Distinctiveness, Uniformity and Stability (PBR legislation)	PGRFA	Plant Genetic Resources for Food and Agriculture
FAO	Food and Agriculture Organisation of the United Nations	PVP	Plant Variety Protection
GATT	General Agreement on Tariffs and Trade	R&D	Research and Development
GRAIN	Genetic Resources Action International	SBSTTA	Subsidiary Body for Scientific, Technical and Technological Advice (CBD)
IATP	Institute for Agriculture and Trade Policy	TRIPS	Trade-Related Aspects of Intellectual Property Rights (GATT/WTO)
IGO	Inter-Governmental Organisation	UPOV	Union Internationale pour la Protection des Obtentions Végétale [International Union for the Protection of New Varieties of Plants]
IFPRI	International Food Policy Research Institute	WIPO	World Intellectual Property Organisation
IPGRI	International Plant Genetic Resources Institute	WTO	World Trade Organisation
IP	Intellectual Property		
IPRs	Intellectual Property Rights		
ISNAR	International Service for National Agricultural Research		

Glossary

Biological resources - includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity¹

Distinctness - clearly distinguishable in one or more important characteristics from any other plant variety²

Essentially biological processes - in plant biotechnology these can include multi-step processes consisting of the genetic modification of plant cells, the subsequent regeneration of plants and the propagation of these plants³. Some definitions are more restrictive: "any process which, taken as a whole, exist in nature or is not more than a natural ... breeding process"⁴

Genetic material - material of plant, animal, microbial or other origin containing functional units of heredity¹

Genetic Resources - genetic material of actual or potential value¹

Intellectual property rights (IPRs) - the rights granted by a state

authority for certain products of intellectual effort and ingenuity⁵

Inventive step - not obvious, having regard to the state of the art, to a person skilled in the art³

Novelty - the state of the art comprising everything made available anywhere to the public by means of written or oral description, by use, or in any other way, before the date of filing of the patent application³

Patent - on a product or process confers an exclusive right on its owner to prevent a third party from making, using, offering for sale, selling or importing that product or a product obtained directly from that process, without the owners' consent⁶

Prior Informed Consent - (from states and/or communities) means that agreement has been obtained by those taking genetic resources from the providers of the resources about the destination of those resources, what they may be used for and, usually, a commitment to share any benefits derived from the enhanced use of those resources.

"*on the public*" concerns the fundamentals from which one cannot derogate without endangering the institutions of a given society....Morality is a different concept"⁷

Stability - means the relevant characteristics remain unchanged after repeated propagation²

***sui generis* system of rights** - an alternative, unique form of intellectual property protection, designed to fit a country's particular context and needs. It can have a wider meaning to cover those aspects of intellectual property not protectable under conventional intellectual property laws, or a system embodying community, farmers' and indigenous peoples' rights³

Uniformity - sufficiently uniform in its relevant characteristics with variation as limited as necessary to permit accurate description and assessment of distinctness and to ensure stability²

Note: Based on Mulvany, 1998. Definitions: ¹CBD, ²UPOV, ³Leiskin 1997, ⁴EU, ⁵OECD, ⁶TRIPS, ⁷WTO

Dates for 1999

	WTO: TRIPS	WTO: Agriculture	FAO	CBD/Biosafety
February	16-17 Council for TRIPS 18-19 Committee on Trade & Environment 25-26 General Council for 3rd Ministerial	18-19 Committee on Trade & Environment 25-26 General Council for 3rd Ministerial		22-23 (tentative) 6th <i>ad-hoc</i> working group on Biosafety 15-19 Extraordinary meeting of COP, Catagena
March	24-25 Committee on Trade & Environment	10-11 Committee on Sanitary Measures 18-19 Committee on Agriculture 24-25 Committee on Trade & Environment	12 Ministerial on Agriculture and small island states	
April	22-23 Committee on Trade & Environment 27-28 Council for TRIPS	22-23 Committee on Trade & Environment	12-16 (tentative) 6th Extraordinary Negotiating Session of the Commission on Genetic Resources for Food and Agriculture 19-23 Commission on Genetic Resources for Food and Agriculture, 8th session	
May				24-28 Subsidiary Body for Scientific, Technical and Technical Advice, Montreal
June	29-30 Committee on Trade & Environment	24-25 Committee on Agriculture 29-30 Committee on Trade & Environment	1-4 Committee on World Food Security, 25th session 24-25 46th Codex	1-3 CBD Intersessional Meeting
July	7-8 Council for TRIPS	7-8 Committee on Sanitary Measures 29-30 Committee on Agriculture		
September	15-16 Council for TRIPS	29-30 Committee on Agriculture		
October	12-13 Committee on Trade & Environment	12-13 Committee on Trade & Environment		4-8 Expert Panel on Access & Benefit Sharing
November	23-24 Council for TRIPS		FAO Conference (Rome)	
December	3rd Ministerial Conference	3rd Ministerial		
Further notes	Article 27.3(b) review	Review of Agriculture (starts last quater)		Jan 2000: Expert meeting on 8(j)