

TRIPS

Consequences for developing countries
Implications for Swedish development cooperation

*Consultancy Report to the
Swedish International Development Cooperation Agency
(Sida)*

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Final Report

Disclaimer

This is a consultancy report to Sida. The views expressed are those of the authors and do not necessarily reflect views held by Sida or -when so referred to- the Swedish Government.

Acronyms

<i>CGIAR</i>	Consultative Group on International Agricultural Research
<i>EMR</i>	Exclusive marketing rights
<i>EPC</i>	European Patent Convention
<i>EPO</i>	European Patent Office
<i>FAO</i>	UN Food and Agriculture Organization
<i>FDI</i>	Foreign direct investment
<i>GATT</i>	General Agreement on Tariffs and Trade
<i>IPIC</i>	Intellectual Property in Respect of Integrated Circuits
<i>IPR</i>	Intellectual Property Rights
<i>LDC</i>	Least Developed Country
<i>OAPI</i>	Organisation africaine de la propriété intellectuelle
<i>OAU</i>	Organisation of African Unity
<i>PBR</i>	Plant Breeders' Rights
<i>PCT</i>	Patent Cooperation Treaty
<i>R&D</i>	Research & development
<i>TRIPS</i>	WTO Agreement on Trade-Related Aspects of Intellectual Property Rights
<i>UN</i>	United Nations
<i>UPOV</i>	Union for the Protection of New Varieties of Plants
<i>WIPO</i>	World Intellectual Property Organization
<i>WHO</i>	World Health Organization
<i>WTO</i>	World Trade Organization

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Preface

The WTO Agreement on Trade-Related Aspect of Intellectual Property Rights (TRIPS) affects areas which are of vital importance for developing countries: agriculture, health care and biological diversity. Consequently, it also affects Swedish development cooperation, for which those sectors are a primary focus.

The Swedish International Development Cooperation Agency (Sida) is increasingly confronted with questions and proposals concerning the relation of the WTO agreements to for example the Convention on Biological Diversity (CBD), national legislation regarding access to genetic resources, FAO's international undertaking on plant genetic resources, and future access to essential drugs. Sida hence finds it essential to increase its own understanding of what consequences the TRIPS agreement may have in developing countries.

To increase the knowledge base within Sida and create a platform for continued work in this area, Sida commissioned this study (see ToR, annex 1). It attempts to describe expected and/or possible implications of the TRIPS agreement for developing countries, with particular focus on three areas:

- plant breeding
- biological diversity, and
- access to medicine.

A further objective of the study has been to analyse consequences of the TRIPS agreement in relation to the overall goals of Swedish international development cooperation. Apart from some general conclusion, the study makes concrete recommendations about how Sida can support developing countries in securing their specific interests and defending their positions in relation to the TRIPS agreement.

As noted by the Swedish trade minister, Leif Pagrotsky, in his keynote speech to a hearing organised by his ministry in September 2000, TRIPS is "one of the most controversial pieces in the WTO legal puzzle" and one of those which "evoke the strongest protests from developing nations". Pagrotsky immediately added, however, that he was prepared to "consider this criticism very seriously and sincerely", stating: "If there are unjust rules they should not be accepted and we need to increase our efforts to modify them as soon as possible". (Pagrotsky, 2000.)

This report is written in the same spirit. However, it should be noted that its focus is much more narrow than that of a trade minister. We have looked at TRIPS strictly from the angle of developing countries and development concerns, not even attempting to balance those against other legitimate perspectives on the agreement. Likewise, it should be emphasized that the report deals with TRIPS only. It is not an overall analysis of IPR issues, not even of development perspectives on IPRs.

We would also like to note that the assignment was relatively short, spanning roughly one month of work for each of the authors. By necessity, this means that the text is uneven in character and partly less well digested than we would have wished. By the same token, we have relied heavily on some other, more in-depth studies available. The work of professor Carlos Correa deserves special mention, and is also our first recommendation for anyone wishing to study the issues further (Correa, 2000). The substantial overview produced by UNCTAD has also been very helpful (UNCTAD, 1996), and for a shortcut to IPR and development issues generally, the annotated bibliography by Graham Dutfield is highly useful (Dutfield, 2000).

While this final report is dated August, 2001, the study is almost exclusively based on information published before the end of 2000. For those interested in following the developments in this field since then, we recommend the websites presented in Annex 3.

Executive summary

This study attempts to identify the main implications of the TRIPS agreement for developing countries, with particular focus on three areas:

- plant breeding
- biological diversity, and
- access to medicine.

A further objective of the study has been to analyse consequences of the TRIPS agreement in relation to the overall goals of Swedish international development cooperation.

The study gives a brief overview of what intellectual property rights are and of the different forms of IPR and IPR legislation today and prior to the TRIPS agreement. The TRIPS agreement is then described, with focus on new obligations, implementation deadlines, review provisions, main implications for developing countries, and concern raised by developing countries in relation to TRIPS.

The TRIPS Agreement

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was negotiated during the Uruguay Round and adopted together with the other new WTO agreements. It forms part of the general institutional framework of the WTO set up through the new GATT in 1994. TRIPS establishes for the first time a global minimum standard of IPR protection. It hence represents a major departure from the previous level of international IPR coordination, which was not set up to standardise IPR legislation between countries but to guarantee non-discrimination in national patent systems.

Firstly, TRIPS makes it mandatory for WTO members to provide most of the existing types of IPR protection - patents, copyright, trademarks, trade secrets, industrial designs, layout designs of integrated circuits and geographical indications. The exceptions are utility models and plant breeders' rights. (However, TRIPS members are obliged to provide some kind of effective plant variety protection.) Secondly, it specifies detailed requirements for the substantive content of national IPR legislation regarding for example extent of coverage, terms of protection, and mechanisms of enforcement. Thirdly, it brings national IPR legislation under the coverage of WTO dispute settlement procedures, which include the option of cross-retaliation in cases of non-compliance.

Implications for developing countries

There was very little opportunity for most developing countries to influence the negotiations of the TRIPS agreement. It is likely that a majority did not have a thorough understanding of its implications by the time they accepted the agreement text.

TRIPS had marginal practical implications for most developed countries. For nearly all developing countries, in contrast, TRIPS has considerable implications. For most developing countries, there will

be a need for new legislation and perhaps even more for strengthening capacity in the judiciary, in customs, and in the police force. The direct costs of implementation of TRIPS in developing countries will be considerable and will compete for resources with other development needs.

Potential benefits of TRIPS for developing countries are discussed. These include possible increase in attraction of foreign direct investment and the possibility that TRIPS might provide a measure of legal protection against bilateral pressures to strengthen IPR legislation above TRIPS levels.

Concerns of developing countries

Since the signing of the TRIPS agreement, developing countries have raised a range of different concerns regarding its implications. A number of these are discussed. The discussion is divided into three parts, dealing in turn with general concerns, concerns related to biodiversity and agriculture, and concerns related to health care.

GENERAL CONCERNS

One of the major concerns raised by developing countries relate to the balance of interests achieved under TRIPS. The conceptual basis of IPR protection presupposes a balance between the time-limited monopoly granted to inventors, and the total benefits to society of the increased inventive activity. A number of developing countries have questioned whether this balance can be achieved under the present TRIPS text.

Other major general concerns are review procedures to be followed, implementation deadlines, WTO rules on non-violation complaints, human rights compliance of TRIPS, and bilateral pressures on developing countries to 'overcomply', i.e. implement IPR legislation beyond the TRIPS agreement.

CONCERNS RELATED TO BIODIVERSITY AND AGRICULTURE

The life patenting provisions in Article 27 of TRIPS have raised the most widespread concerns among developing countries. Patents on living organisms may over time bring profound changes in the way biological resources are controlled and exploited. The potential effects are relatively more important for developing countries because agriculture and other natural resource based livelihoods are still a major part of their economies, but also because biodiversity is one of few areas where they have a comparative advantage which could form the basis of indigenous economic development.

The formal submissions from developing countries to the TRIPS council regarding life patents center on issues related to control over research and development, biopiracy, the right to save and exchange seed and ethical, religious and cultural values. Other implications discussed are possible interpretations of the *sui generis* plant variety protection in TRIPS, and the relation of TRIPS to national sovereignty of genetic resources and sharing of benefits as laid down in the Convention on Biological Diversity. There are likewise concerns about the consequences of TRIPS for the multilateral system for facilitated access to plant genetic resources currently being negotiated in the framework of the International Undertaking on Plant Genetic Resources. Finally, protection of traditional knowledge in relation to the TRIPS agreement is discussed.

CONCERNS RELATED TO HEALTH CARE

Many developing countries did not grant patents on pharmaceuticals prior to the TRIPS agreement. Some countries have granted process patents but not product patents, others no patents at all. Under

TRIPS, no exclusions are allowed for pharmaceuticals. The major concerns of developing countries related to health care are that generic drug-producing firms in developing countries will be forced out of the market, that drug costs will increase and further restrict drug access in developing countries, and perhaps most important of all that the strengthened IPR regimes will result in increased proprietarisation of drug research, and that this will further restrict research and development of remedies for major diseases in developing countries.

Exceptions in TRIPS to exclusive rights are discussed, and their potential use to accommodate the needs of developing countries. These relate to e.g. experimental use of patented products, parallel imports and compulsory licensing. Finally, the potential implications of TRIPS on the use of traditional medicine is discussed.

Conclusions

This study concludes that the minimum global standard of IPR protection achieved by TRIPS is not likely to bring any substantial benefits for developing countries. The optimal IPR strategy for developing countries would very likely be the same one that developed countries used during their industrial development process: gradual development of IPR systems, implementation of forms of protection tested by experience in other countries, adaptation of those to national requirements, creation of own sui generis forms when needed, and cooperation on a voluntary basis to achieve an increasing measure of international coordination.. This is a strategy that TRIPS does not allow. The space for experimentation with levels and forms of protection which used to exist is no longer available.

Implementation of TRIPS will also have substantial costs for developing countries, although the size of those costs is impossible to establish with any accuracy.

From a development perspective, it seems clear that what is needed in TRIPS is increased flexibility for developing countries to design IPR laws and decide on levels of protection. The study has found no substantial development-related arguments to defend the TRIPS agreement in its present form.

It is likely that some of the modifications to TRIPS which are desirable from a development perspective will conflict with the interests of developed country export industries. This study has not attempted to balance the different interests, since it falls outside its remit.

There are several options which would restore more or less of the flexibility in IPR legislation removed by TRIPS. The most radical solution, but also in many ways the simplest, would be to repeal the agreement and revert to the previous system of IPR coordination by way of the separate intellectual property treaties administered by WIPO. This could in fact be helpful in the long term to the WTO as an organisation. As widely recognised, TRIPS is a foreign element among the WTO agreements, since it prescribes minimum standards for domestic legislation rather than setting maximum limits for trade barriers.

Another option which would involve more work for the WTO is to renegotiate TRIPS on a less ambitious level, reducing commitments to clearly trade-related aspects.

A third possibility is to make TRIPS and other new additions to the WTO framework optional for its members. This way, an entirely different negotiating dynamic would be created.

Finally, as an absolute minimum, and something that should be self-evident, there is a need to clarify that developing country members have the right to use existing flexibility in the TRIPS without

interference and over-compliance pressures from developed country members.

Recommendations

The overall recommendation to Sida is to assist developing countries in any way possible to preserve and/or restore maximum flexibility in the design and level of national IPR protection.

There are two main avenues for Sida to assist with this. First, and potentially most important, to act on a policy level to influence the Swedish government's position in relevant aspects. Second, to offer direct assistance to developing countries in this context.

At least the following policy options should be taken up for consideration by the international community, and as appropriate supported by Sida in its dialogue with the Swedish government:

- To repeal TRIPS and return international IPR coordination to WIPO
- To renegotiate TRIPS with a strictly trade-related focus
- To abandon the single undertaking and make TRIPS optional for WTO members
- To allow wider exceptions to patentability, including
 - general exceptions with less restrictions
 - living organisms
 - pharmaceuticals
- To require the following references in patents covering living organisms:
 - sources of the genetic material
 - sources of traditional knowledge used to obtain material
 - evidence of fair and equitable benefit sharing
 - evidence of prior informed consent to patenting from previous holder
- To require inclusion of traditional knowledge as prior art in patent examination
- To expand the scope of geographical indication protection beyond wines and spirits
- To clarify the right to use existing flexibility in the agreement, in line with Article 1

Apart from raising the policy options above in the dialogue with the Swedish government, Sida should support:

- Studies on the implications of repealing the TRIPS agreement;
- Targeted information and awareness raising of government ministries and authorities in their respective fields in respect of international trade agreements and intellectual property rights;
- Actions to increase the coherence of developing country policies, e.g. by workshops and training across ministries and departments, bringing together e.g. ministers of health, agriculture and trade to reach a common understanding of critical issues and of the interrelated nature of economic and social welfare and human rights;
- NGO efforts to raise awareness of the general public and of governments in developing countries;
- Developing country governments' development of IPR legislation and policies and in particular assist in the full use of options available at present in TRIPS to promote a fair balance of interests;
- Development of innovative and workable ways of protecting indigenous and traditional knowledge as part of developing country sui generis legislation, and the exchange of experience between governments regarding problems and achievements in the implementation of such legislation.

Intellectual property rights

Intellectual property rights (IPR) are similar in most respects to property rights over tangible, physical objects. To own property means, typically, to have a right to use it, a right to exclude others from using it (entirely or partially), and a right to transfer these rights to others. The exact content of property rights can vary considerably between different property systems and different kinds of property. Property rights also often come with certain obligations.¹

However, intellectual property rights differ in one fundamental respect. The intangible, abstract objects constituting intellectual property have no natural, self-defining boundaries like physical objects do. In fact, they do not even exist until they are created by explicit definition and designation. For this reason, in addition to general property legislation, IPRs are covered by specific legal systems, and most forms of IPR require a specific registration procedure. Applications need to be made and examined by specialists in order for an IPR to be established. Frequently the exact boundaries of an IPR subsequently becomes the subject of litigation between the holder and holders of related IPRs. In short, the transaction costs of acquiring and holding IPRs are much higher than for ordinary physical property.

While the subject matter of intellectual property is intangible objects such as information, knowledge or ideas, intellectual property rights are expressed in practice as rights over the tangible products resulting from those intangible objects. For example, an industrial patent confers the exclusive right to manufacture the protected product or use the protected process, and a copyright the exclusive right to perform the protected work of art or multiply it in the form of books, compact discs, etc.

TYPES OF INTELLECTUAL PROPERTY RIGHTS

The main categories of intellectual property rights are:

- *Patents.* As the strongest form of IPR, patents are awarded subject to a thorough examination procedure. They confer a very high level of exclusive rights over an invention for a period of 20 years from the date of the application. Any use of the patented matter, except strictly private use, requires permission (licence) from the owner. To receive a patent, an invention must fulfil three main criteria: novelty, non-obviousness (inventive step) and industrial applicability (usefulness). A detailed description of the invention must be submitted, which becomes public after the grant of the patent.
- *Copyrights.* As the name implies, and in contrast to patents, copyrights do not protect the intellectual content itself, only the reproduction of that content in tangible form. Copyright is granted without any registration or application procedure to authors of original works, and also to computer software and databases. A copyright holder cannot prevent others from using the copyrighted material in development of other original works, as long as it is not directly copied. The term of protection is normally the life of the author plus 50 years, or 50 years only when the author is a corporate body.
- *Trademarks.* Names, signs and symbols used to identify goods or services can be registered as trademarks. There is no limit to the term of protection as long as the trademark continues to be used.
- *Trade secrets.* The right to keep trade secrets (confidential business information, undisclosed information) is protected through civil and/or criminal law. In the nature of the case, there is no registration procedure, nor is there any exclusive right guaranteed.

¹ For a discussion about the concept of property, see for example Becker (1980) and Snare (1972).

- *Industrial designs*. The form of an industrial product can be protected. Exact requirements for protection vary widely between countries.
- *Layout designs (topographies) of integrated circuits*. A recently created sui generis² IPR similar to copyright, although with much shorter term of protection, typically 10 years. Only the right to reproduction and distribution is protected, not use in further research and development.
- *Plant breeders' rights*. A sui generis IPR specifically created to protect new plant varieties. Varieties can be registered provided they are new, stable, homogenous and distinguishable. Protection is similar to a copyright in that it protects the rights to sell and distribute propagating material, while use of the protected variety in further breeding and development is not restricted. The term of protection is comparable to that for patents, around 20 years.
- *Geographical indications*. Typically used for food products and in particular for wines and spirits, these are signs or names which indicate that a product or service originates in a particular geographical location.
- *Utility models*. Sometimes referred to as *petty patents*, this more unusual form of IPR provides protection for models and designs. Although there are normally requirements for novelty and inventive step, these are less strict than for patents, and examination is simpler or sometimes non-existent. The term of protection is correspondingly shorter, typically less than 10 years.

CONCEPTUAL BASIS OF INTELLECTUAL PROPERTY RIGHTS

While property rights over tangible objects go very far back in human history, intellectual property rights are a much more recent phenomenon, closely associated with the development of industrial societies. In most pre-industrial societies, individual ownership of information or knowledge was/is a foreign concept.

The various types of IPRs have developed from partly different rationales. Some of the simpler forms, such as trademarks and geographical indications, aim mainly at ensuring fair competition by protecting against misleading claims in marketing.

Some IPR forms are conceived partly as moral rights, in particular the copyright of individual authors.

However, for all IPR forms which confer exclusive rights, the conceptual basis is a purely economic one. This is especially clear in the case of patents.

In a market economy, granting exclusive rights to certain producers is obviously a major deviation from the principle of free competition. In a competitive environment, when a new product enters the market, competing producers would be expected to copy and/or further develop that product, thus increasing benefit to consumer by offering lower prices, an improved product, and/or a wider range of choice. Granting patent rights to the original producer eliminates competition in all those respects.

The rationale for doing so is the so-called free rider problem. Especially where a major, long-term research and development effort is involved in creating the original product, it is obvious that second comers will have a considerable competitive advantage if they can freely use the results of that effort without sharing the cost. The effect may be that original inventors cannot recuperate their investment, and over time this may become a disincentive to innovation, slowing the rate of development.

Patent systems are an attempt to solve this problem. The assumption is that by granting a time-limited monopoly, the original inventor will be able to recover the research and development investment. In exchange, the publication requirement assures that at the end of the patent term, the invention will be freely available and normal competition can resume. In theory, the system should be balanced in such

² Sui generis, "of its own kind", is a term commonly used to indicate a form of IPR created for a specific purpose or field of technology.

a way that total economic benefits to society of the innovations created outweigh the economic costs of the monopoly.

The actual distribution of benefits from the patent system is still an unresolved issue. Empirical studies have failed either to prove or disprove that patents work as intended (Correa, 2000).

IPRS STRONG IN DEVELOPED ECONOMIES

It should come as no surprise that IPR systems historically were first developed in countries with strong industrial research and development, and that countries dependent on importing technology have been reluctant to grant strong IPRs. In the early 19th century, industry in the newly formed USA developed largely on the basis of unauthorised use of British technology. In the last 50 years, first Japan, then Korea, Malaysia and other Asian countries have based their industrial development on imitation of mainly US and European products. Only after reaching the level where they themselves became producers of new technology have they introduced stronger IPR protection. It should also be noted that many developed countries, including Sweden and Switzerland, now among the world leaders in pharmaceuticals, introduced patent protection in this field only in the 1970s, being free until then to pursue imitation-based development.

Today, with developed economies aiming to become 'knowledge societies', IPRs are acquiring an even more central role. For economies concentrating on research and development, increasingly leaving actual production of the resulting tangible goods to others, strong IPR protection is becoming a key production factor, when they no longer sell the goods as such, only their intellectual property component. A former US Commissioner of Patents and Trademarks recently went so far as claiming that Adam Smith's three pillars of wealth – labor, capital, and natural resources – now need to be joined by a fourth, intellectual property (Mossinghoff & Kuo 1998).

The vast majority of all IPRs globally are consequently held by developed country owners, reflecting the very uneven distribution of research and development activity. In the USA, 95 percent of all patents in the period 1977-1996 were granted to applicants from 10 industrialised countries, while applicants from developing countries accounted for less than 2 percent (Kumar 1997). In developing countries, this also means that typically only a small fraction of IPRs are held by national owners or cover nationally developed technology. Most IPRs granted by developing countries protect technology developed abroad and held by foreign owners.

INTERNATIONAL COORDINATION OF IPR SYSTEMS

With few exceptions, IPR systems are national. Applications have to be submitted in each country separately, and rights granted are only valid in that country.

One of the exceptions is Europe, where patent laws are coordinated through the European Patent Convention (EPC) and a common European Patent Office (EPO) can grant patents valid in all member states. Legally, these are however still separate national patents, possible to challenge separately under national law. The EU Commission however recently tabled a proposal to establish a 'community patent'. This would also be granted by the EPO but be automatically valid in all EU member states and only be possible to challenge at the European Court of Justice. Another exception is West Africa, where a regional patent office was created immediately at independence in the 1960s, instead of setting up national offices. This office, l'Organisation africaine de la propriété intellectuelle (OAPI), is the only patent office which actually grants supra-national patents. There are also regional patent offices in East Africa and in the Commonwealth of Independent States (former Soviet republics).

Not surprisingly, there is considerable variation between countries in IPR protection. Not all types of IPRs are available everywhere, and when they are, many details such as allowable subject matter, term

of protection and registration procedure may differ. As already indicated, there is a strong correlation between level of IPR protection and level of industrial development. Some of the sui generis IPR forms, such as those for integrated circuits or plant varieties, exist in few or none of the developing countries, and patent systems are typically more limited in terms of patentable matter and often require more of the patent holder, for example local working of the patent.

There is however a long history of international coordination between national IPR systems.³ The oldest international IPR treaty is the Paris Convention, in effect since 1884. It covers patents, trademarks and industrial designs, and has over 150 member states. A second major IPR treaty is the Berne Convention on copyright.

The Paris Convention established three important principles. Firstly, it requires "national treatment" also for foreign nationals, that is, no discrimination against them in domestic patent legislation. Secondly, it provides for an international "right of priority" in the form of a grace period of one year from the date of the first patent application, during which applications can be made in any other member state using the filing date of the first application. And thirdly, it binds members to respect those two principles in any subsequent multilateral or regional patent agreements they may enter into. Under these basic rules, incidentally quite similar to the basic trade principles established by the GATT some 70 years later, most national and patent and trademark systems have been open to foreign applicants since the entry into force of the Paris Convention in 1884.

What the Paris Convention has not done, neither initially nor in subsequent renegotiations, is standardise the substance of patent protection. It does not include requirements regarding patentable subject matter, patent terms, use of compulsory licensing, principles for claim interpretation or enforcement, to mention some of the main aspects in which patent systems differ. This has been left to the discretion of national legislators.

What was originally the secretariat of the Paris Convention evolved over time to take responsibility for international coordination of IPR matters more generally, and in 1967 formally became a UN agency, the World Intellectual Property Organization (WIPO). Current membership is almost universal, with over 200 member states.

In 1978, a further addition to the international IPR framework came into force, the Patent Cooperation Treaty (PCT), which provides the possibility to file a single patent application for protection in multiple countries. While final examination is still done nationally according to national legislation, and may thus result in different decisions, the PCT process greatly reduces the effort required of the applicant. There are currently around 100 member states. The PCT is also administered by WIPO and has rapidly grown to become a major part of its total activity, simultaneously generating a considerable surplus from application fees.

This was the status of international IPR coordination before the negotiation of the TRIPS agreement.

³ For a good historical account, see Mossinghoff & Kuo (1998).

The TRIPS agreement

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was negotiated during the Uruguay Round and adopted with the other new WTO agreements in Marrakech in 1994. It forms part of the general institutional framework of the WTO set up through the new GATT in 1994. It is administered by a separate Council for TRIPS.

Despite its modest-sounding name, TRIPS is not limited to 'aspects' of the IPR system. It represents a major departure from the previous level of international IPR coordination. As we have seen, the previously existing framework of WIPO-administered treaties was set up to guarantee non-discrimination in national patent systems, not to standardise IPR legislation between countries.

What TRIPS does is establish for the first time a global minimum standard of IPR protection. This standard is set at a very high level, incorporating "most of the standards of protection on which developed countries could agree among themselves" (Reichman 1998).

Firstly, TRIPS makes it mandatory for WTO members to provide almost all existing types of IPR protection. The only exceptions are utility models and plant breeders' rights. Secondly, it specifies detailed requirements for the substantive content of national IPR legislation regarding for example extent of coverage, terms of protection, and mechanisms of enforcement. Thirdly, it brings national IPR legislation under the coverage of WTO dispute settlement procedures. This means that non-compliance can lead to cross-retaliation in any field of trade.

New obligations

The following are the most important new obligations created by TRIPS.

GENERAL

- WTO members must provide IPR protection in the forms of patents, copyright, trademarks, trade secrets, industrial designs, layout designs of integrated circuits and geographical indications.
- IPR laws must respect the principle of 'national treatment', as defined in the Paris Convention. This is one of the most long-standing principles of international IPR coordination.
- IPR laws must respect the principle of 'most-favoured-nation', as defined by the GATT⁴. This is a novelty in international IPR coordination, previously used primarily in trade contexts.

PATENTS

- Patents must in principle be granted in all fields of technology without discrimination.
- Exclusions from patentability are only allowed for
 - inventions threatening *ordre public* or morality
 - diagnostic, therapeutic and surgical methods
 - plants and animals other than micro-organisms
 - essentially biological processes for the production of plants or animals.

⁴ The most-favoured-nation principle means that an advantage granted to one WTO member must be extended to all other members.

- However, as an exception to the exception for biological processes, "non-biological and microbiological processes" cannot be excluded from patentability.
- Moreover, if patents are not granted for plants, there must be "an effective sui generis system" for protection of plant varieties.
- Patents must be granted both for products and for processes, and process patents must imply so-called 'product-by-process' protection (exclusive rights to a process automatically gives exclusive rights over its direct products).
- In case of litigation over process patents, reversal of the burden of proof normally applies (the alleged infringer must prove *not* to have used the patented process).
- The minimum extent of exclusive rights is defined.
- The term of protection must be at least 20 years from filing date.
- Compulsory licensing is only allowed provided a number of conditions are fulfilled.

COPYRIGHTS

- Copyrights must be protected in accordance with the Berne Convention (with the exception of moral rights to works).
- Computer programs must be protected as literary works.
- Compilations of data must be protected as such (independent of any copyright on the data involved).
- Rights to control rental of copyrighted works must be protected at least for phonograms, computer programs and some cinematographic works.
- For copyright holders which are not natural persons, the term of protection must be at least 50 years.
- Exceptions must be limited to special cases.

TRADEMARKS

- Detailed rules are laid down for what signs may be protected.
- Term of protection must be at least 7 years and indefinitely renewable.
- Exceptions must be limited.
- At least three years of non-use must be allowed before registration is cancelled (or more, if the owner can produce valid reasons).

TRADE SECRETS

- Trade secrets (undisclosed information) must be protected by law.
- Secret data submitted for approval of new pharmaceutical or agrochemical products must be protected by government agencies.

INDUSTRIAL DESIGNS

- New or original designs must be protected (either on the basis of novelty or originality).
- Term of protection must be at least 10 years.

INTEGRATED CIRCUITS

- Layout designs of integrated circuits must be protected in accordance with the Washington Treaty of 1989 (IPIC Treaty).
- Protection shall extend to products incorporating protected circuits.
- Term of protection must be at least 10 years.

GEOGRAPHICAL INDICATIONS

- Some form of protection must be provided for geographical indications.
- Stronger requirements are specified for protection of wines and spirits.
- Negotiations shall be initiated to create a multilateral registration system.

ENFORCEMENT

- Judicial enforcement of IPRs must be provided, and quite detailed requirements are specified regarding procedures, the authority of the judiciary to order damages and other remedies, and provisional measures to halt alleged infringement.
- Additionally, there is an obligation to provide specific procedures for suspension of imports of suspected "counterfeit trademark or pirated copyright goods".
- Criminal procedures and penalties must be provided at least regarding wilful trademark counterfeiting and copyright piracy on a commercial scale.

DISPUTE SETTLEMENT

- TRIPS is subject to the general GATT rules about dispute settlement. This means that if a member state is found guilty of non-compliance by a dispute settlement panel, the complaining member(s) can be allowed to apply trade sanctions. These can be applied in any field of trade and need not have any relation to IPRs.

Implementation deadlines and review provisions

TRIPS entered into force on 1 January 1995. The general deadline for implementation was one year after that, 1 January 1996.

Without any delay, however, those countries not providing patents for pharmaceuticals and agricultural chemicals were required to set up a means for filing applications in this field, to be processed once patent protection is introduced. They must also grant "exclusive marketing rights" (EMR) for the products covered by such applications for 5 years or until a patent is granted or rejected, whichever occurs first. EMR is an ad hoc concept peculiar to TRIPS, and their exact scope is not defined.

Except for the provisions on national treatment and most-favoured-nation treatment, which had to be implemented on the general deadline, all developing countries were granted an additional four year delay in application, until 1 January 2000. Some economies in transition also benefit from this later deadline.

For least developed countries, the additional delay was extended to 10 years, until 1 January 2006.

There is also a special provision for those developing countries which did not previously grant product patents in certain fields of technology. They have until 1 January 2005 to fulfil their obligations in this respect.

In addition, there are built-in review provisions in TRIPS which partly overlap with the implementation deadlines.

The term "review" is used in four different senses within the agreement:

1. Review of the implementation process in individual member states. These reviews are now underway for developing countries.
2. General review of the implementation of the agreement by the TRIPS Council, with a view to identifying needs for modification or amendment. A first such review is mandated to start immediately after the expiration of the extended implementation deadline for developing countries (1 January 2000). It will then be repeated with two year intervals.
3. Continuous review of the section on geographical indications, with a view to facilitating its operation.
4. Specific review of the provisions of subparagraph 27.3(b) on the extent of patent protection on living organisms. This process was to be initiated 1 January 1999 but started late and is still ongoing in TRIPS Council.

The negotiation process

TRIPS was one of the most contentious parts of the Uruguay Round negotiations. The original understanding, reflected in the negotiating agenda approved at the initial Ministerial in Punta del Este in 1986, was that IPR issues would be part of the negotiation mainly as they related to trade in counterfeit goods (infringement of trademarks or copyrights). This is the only subject matter which is specifically mentioned in the Punta del Este Declaration. There is no reference to development of binding global standards for IPRs.

Developed countries however soon presented negotiating proposals aiming to develop such standards for most types of IPRs. Developing countries refused for several years to enter into such negotiations. When they finally yielded, it was very reluctantly and due to mounting pressure from developed countries, often including threats of bilateral trade sanctions.

The negotiation process itself was similarly asymmetric. In terms of participation, key parts of the negotiation were conducted in a small drafting group composed of five developed and five developing countries, with occasional reference to a broader reference group of ten countries from each side. In practice, this meant that a majority of developed countries had direct representation (EU, USA, Japan, Canada regular members), but only a small fraction of developing countries (Brazil, Argentina, and India regular members). In terms of negotiating capacity, the odds were still more uneven, with developing countries having very little technical support, while developed countries could draw on their virtually unlimited IPR competence.

Because the final result of the TRIPS negotiation was then presented to the full GATT membership as part of the "Dunkel Draft" package deal in 1991, there was very little real opportunity for most developing countries to influence the content of the agreement. In fact, it is likely that a majority did not even have a proper understanding of its implications by the time they accepted the text.

Main implications for developing countries

TRIPS had limited practical implications for most developed countries. Although there were areas where some developed countries had to adjust or complement existing IPR legislation in order to comply, none were faced with substantial new requirements. In all important respects, the agreement was negotiated to accommodate both the levels and the technical design of existing IPR protection in developed countries.

For nearly all developing countries, in contrast, TRIPS has very considerable implications. Because strong IPR protection, for obvious reasons, is an interest of economies strong in industrial research and development, it follows that developing countries as a group have considerably weaker IPR legislation than developed countries. TRIPS will require substantial new legislation and infrastructure investment in practically all developing countries.

There is however wide variation also within the developing country group, again depending on their level of industrial research and development. Typically, the economically stronger developing countries already provide most forms of IPR protection and are members of the Paris Convention and other relevant treaties. For them, while the detailed standards of TRIPS may imply substantial additions and changes to national IPR systems, it normally will not as a rule require entirely new legislation or infrastructure. In contrast, the economically weaker developing countries, and in particular the least developed countries (LDCs), often lack several types of IPR entirely and face very heavy new obligations.

IPR legislation

TRIPS requires stronger IPR legislation of most developing countries. The exceptions are those countries which already adopted new IPR laws incorporating the components of TRIPS during the years immediately preceding the agreement. This was the case with several of the more industrially advanced developing countries, particularly in Latin America. Often strengthened IPR laws were negotiated as a part of bilateral trade agreements with the USA.

This section highlights the areas where TRIPS makes major new demands on IPR legislation in developing countries. Focus is on the new requirements in the patent field. This is no doubt the area where TRIPS makes the most difficult demands. The patent provisions of TRIPS are also the only ones directly relevant for the specific focus of this study: agriculture, biodiversity and health. The provisions regarding other forms of IPRs have not been looked into in any detail.

PATENTS ON PHARMACEUTICALS

The basic principle of TRIPS is that no field of technology can be excluded from patentability unless this is explicitly allowed. One key field where many developing countries have not previously granted patents is pharmaceuticals. Some countries have granted process patents but not product patents, some no patents at all. Under TRIPS, no exclusions are allowed for pharmaceuticals.

LIMITS TO COMPULSORY LICENSING OF PATENTS

Compulsory licenses are a mechanism for forcing a patent holder to allow use of the patented invention. By default, part of the exclusive rights of a patent holder is the right to block use of the invention entirely by refusing to license it. A compulsory license is typically used to override this refusal in order to make the invention available for local production, or to make it available for competing producers to stimulate price competition. In other words, it is one of the mechanisms for limiting the patent holder's monopoly. TRIPS now specifies that compulsory licenses can only be used provided a number of conditions are fulfilled. In practical terms, this makes it more cumbersome for a country to use them, although TRIPS does not in fact limit the range of grounds on which compulsory licenses may be granted.

PROCESS PATENTS EXTENDED TO PRODUCT

A differentiation between process and product patents has been used by a number of developing countries as a means to restrict the exclusive rights of the patent holder. With the requirement to give "product-by-process" protection this possibility is eliminated. This requirement has special relevance for developing countries in the context of life patenting, as explained below.

REVERSAL OF BURDEN OF PROOF FOR PROCESS PATENTS

In case of alleged infringement of a process patent, TRIPS requires that the burden of proof must fall on the alleged infringer. In other words, the accused must prove his innocence. This is a corollary to the "product-by-process" provision and serves the same purpose, to strengthen the rights of the process patent holder. Again, it will be especially relevant for life patents.

PATENTS ON LIFE: GENERAL

Few developing countries offer any patent protection for living organisms. Under TRIPS, they are required to extend patents to some life forms. Exactly where the limits will be drawn is difficult to predict, as will be seen from the following.

Patents on living organisms as such were only very recently allowed in most developed countries, starting in the USA in the 1980s. Previously, only microbiological processes could be protected by patents, and the microorganisms involved only through product-by-process. For plants, IPR protection was available only through plant breeders' rights, not by patents. For animals, there was no IPR protection at all.

The rationale for extending the patent system first to microorganisms as such, and later also to plants and animals, was the advent of genetic engineering and related techniques. These techniques allowed a higher level of technical intervention judged by many developed country patent offices to meet the criteria for a patentable invention in a way traditional breeding techniques did not. A supporting argument was that the high research and development cost involved in new biotechnologies made a higher level of IPR protection necessary.

The TRIPS provision regarding the limits to life patents is closely modeled on European legislation (the European Patent Convention; EPC). It reads

Members may also exclude from patentability... plants and animals other than micro-organisms, and essentially biological processes for the production of plants and 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.

It is not entirely clear from this text what the limits to life patenting will finally be under TRIPS, but a number of things can be safely concluded or reasonably assumed, as specified below.

PATENTS ON LIFE: MICROORGANISMS

In the case of microorganisms the text is quite unambiguous. Protection must be provided for microorganisms as such by product patents. What is open to discussion, however, is what "microorganism" means. In biological terms, it would normally include unicellular organisms such as bacteria, fungi, algae and protozoa, and sometimes viruses would be included. In most developed countries, however, present patent practice also includes plant and animal cell cultures (including human cultures), as well as sub-cellular entities such as plasmids. As TRIPS does not define "microorganism" it will be up to future clarification either in TRIPS Council or dispute settlement to decide where the line will finally be drawn.

PATENTS ON LIFE: PLANTS AND ANIMALS

In the case of higher organisms, it is clear that there is no obligation to provide product patents on plants and animals as such. There is however an obligation to provide either patents or some sui generis protection (see below) for plant varieties.

There is also an obligation to provide patent protection for "non-biological" and "microbiological" processes for the production of plants and animals, while "essentially biological" processes for this purpose may be excluded from patent protection. Again, none of these terms is defined in TRIPS, but all are modelled either on the text or on present implementation of the EPC.

"Essentially biological" processes are in Europe understood to mean traditional cross-breeding of plants and animals, using normal sexual propagation without major technical intervention.

"Microbiological" processes are understood to mean all processes performed on "microorganisms" in the wide sense related above, that is, including plant and animal cell cultures. "Non-biological" processes, finally, are those where major technical intervention, such as gene technology, is involved. When a process is composed of several steps, it is considered sufficient that one step is "microbiological" or "non-biological" for the whole process to qualify as such.

There is nothing to say that the WTO process need necessarily adopt these European definitions. On the other hand, as much of the text was drawn from that source when the agreement was negotiated, it does seem quite plausible that guidance for its interpretation may be sought in the same direction.

If so, any process involving either plant and animal cells ("microorganisms"), or gene technology or related biotechnologies ("non-biological" processes), must be patentable. By extension (product-by-process), any direct product of such a process must also be covered by that patent. And under the provision about reversal of the burden of proof, anyone attempting to sell this product would be required to prove that it was not produced by the patented process. Although formally still a process patent, the protection provided would be very close to an actual product patent.

In practice, this would mean, as is already the case in Europe, that most plants and animals modified by modern biotechnologies would become patentable under TRIPS by this route⁵.

⁵ In Europe, plants and animals are now also increasingly protected by direct product patents. This other route depends on a slight difference in wording, and is therefore only possible under the EPC, not under TRIPS. While TRIPS allows exclusion for "plants and animals", the EPC excludes only "plant and animal varieties". Narrowly interpreted, this allows patenting of any other category of plants and animals than "varieties".

SOME FORM OF PROTECTION FOR PLANT VARIETIES

Unless plant varieties are allowed patent protection, TRIPS requires that protection be provided under some sui generis system. Few developing countries had either kind of protection before TRIPS, so most need new legislation. One alternative is to adopt a Plant Breeders' Rights (PBR) system compatible with the existing UPOV convention. The other is to freely design another system. The only limitation stated in the TRIPS text is that the system implemented must be "effective".

This means that although PBRs are one of the two types of IPRs not directly addressed by TRIPS, the agreement in practice creates a very strong incentive to implement them, or at least something partly resembling them.

COPYRIGHTS

While many developing countries have basic copyright legislation and adhere to the Berne Convention, TRIPS will require them to extend the copyright system to several new areas, such as computer software. As copyright protection does not require an examination and registration system, this expansion does not pose the same administrative challenge as the expansion of the patent system. However, the strict enforcement provisions of TRIPS (see below) may require a major effort in many countries where illegal copying takes place on an industrial scale.

TRADEMARKS

Like copyright legislation, trademark systems are relatively widespread in developing countries, and while TRIPS will probably entail legislative changes almost universally, it will in most cases not require entirely new systems.

OTHER FORMS OF IPR

All the other forms of IPRs are relatively uncommon in developing countries and will require new legislation in most cases.

Enforcement legislation

TRIPS is the first agreement in the IPR field to create direct obligations to enforce the protection granted. It sets standards both for civil and criminal law. In the fields of copyrights and trademarks, it also requires that customs authorities assist right holders in preventing trade with counterfeited or pirated goods. For most developing countries, there will be a need both for new legislation and perhaps even more for strengthening capacity in the judiciary, in customs, and in the police force. Particularly in countries where illegal trade in copyrighted or trademarked goods is widespread, this may be a major implication of TRIPS.

Infrastructure and human capacity

In many cases TRIPS will entail a considerable need for investment in infrastructure and human capacity. New forms of IPR, as well as expansion of existing systems to new fields of protection, will require increased numbers of staff, better training, and new computer and administrative systems. The

expansion of IPRs to living organisms will require access to systems for deposition of biological material and facilities for identification of plant varieties, both entirely new branches of activity for most developing country IPR administrations.

Costs of implementation

Apparently, no attempts at estimating the costs of TRIPS implementation were made prior to the finalisation of the agreement. Some rough estimates done later by UNCTAD and the World Bank (UNCTAD 1996, Finger & Schuler 1999) have not yielded reliable figures but indicate that the costs may be substantial, in the magnitude of 10 or more million dollars per country. Costs can be expected to be relatively higher in less developed countries, because they start from a lower level of IPR legislation. It is likely that in many developing countries, much of this cost will need to be covered by development assistance funds, at least the initial investment in new legislation, infrastructure and human capacity. At any rate, especially in LDCs, TRIPS implementation will directly compete for resources with other development needs.

Benefits of implementation

It is widely assumed, especially at the policy level in developed countries, that strengthened IPR protection will generate economic benefits for developing countries. It has also been argued that this will more than offset the cost of TRIPS implementation. In particular, the importance of strong IPRs for attracting foreign direct investment (FDI) is routinely cited as a key mechanism to this effect.

The scientific literature is however inconclusive on this point.⁶ There are studies which demonstrate some correlation. But there are also studies which document substantial increases in FDI despite weak IPR protection (Kirim 1985, cited in South Centre 1997), and studies which show little correlation between strengthened IPR protection and changes in FDI (see e.g. below pp 35-36). The provisional scientific consensus appears to be that the level of IPR protection most likely is one factor influencing FDI decisions, but far from the only one and not usually the decisive one. With standardisation of IPR protection under TRIPS, differences in this respect will no longer exist and other factors will decide FDI choices. Moreover, it has been argued that the TRIPS agreement may also lead to reductions in the flow of FDI (South Centre, 1997); with stronger IP protection, the risk of imitation will be lower and title-holders may prefer export of products rather than local production in export market countries. It has also been pointed out that any benefits will likely be concentrated in NICs, while LDCs and other countries at the opposite end of the development scale will risk net costs even over the longer term (UNCTAD 1996).

Strictly speaking, however, even if economic benefits from strengthened IPR protection could be conclusively demonstrated, they would not be benefits of TRIPS implementation, but of IPR implementation. Also before TRIPS, developing countries were free to implement TRIPS levels of IPR protection, or indeed higher levels, if they saw fit. None of the potential benefits of IPRs depend on the existence of TRIPS. What would need to be demonstrated are benefits of having mandatory minimum standards of IPR protection, which is the only new contribution of TRIPS.

⁶ For in-depth discussion and many further references, see UNCTAD (1996) and Correa (2000).

In the course of this study, we have been unable to identify any substantial benefits to developing countries of being bound by the TRIPS minimum standards, rather than retaining their freedom to define levels of protection nationally.

No more than two possible benefits have been suggested to us, none of them in our view qualifying as substantial. The first one is that when wanting to attract FDI, there would be some advantage for developing countries in being able to ensure potential investors that their level of IPR protection would not be reduced by future government decisions, because it is dictated by TRIPS obligations. While this is probably true, the difference appears rather marginal.

The second one is that developing countries gained concessions in other parts of the Uruguay Round negotiations, particularly in agriculture and textiles, by making concessions in TRIPS. While correct, this argument, if anything, strengthens the conclusion that TRIPS lacks direct benefits for developing countries. Furthermore, considering that both the agriculture and the textiles agreements largely have failed to deliver the benefits expected by developing countries, it can also be questioned whether the argument is valid at all.

An additional argument which was not suggested to us during interviews, but which we think could be valid, is that TRIPS might provide a measure of legal protection against bilateral pressures to strengthen IPR legislation above TRIPS levels. It is perfectly clear from TRIPS Article 1 that members are under no obligation to offer any kind of IPR protection in excess of TRIPS requirements. In principle, it should be possible for developing countries to use this language (and various substantive provisions in later articles) to defend themselves against such pressure, including by use of dispute settlement procedures. In practice however, it remains to be shown that this is a workable approach. Experience to date, as discussed below, is that developed countries repeatedly and successfully, in spite of TRIPS provisions, have applied pressures to prevent developing countries from using the flexibility provided by the agreement, for example regarding the use of compulsory licensing and parallel imports.

Concerns raised by developing countries

Developing countries have raised a range of different concerns with the TRIPS agreement. A number of these are discussed in this section. It is divided into three parts, dealing in turn with general concerns, concerns related to biodiversity and agriculture, and concerns related to health care.

General concerns

BALANCE OF INTERESTS

As mentioned above, the conceptual basis of IPR protection presupposes a balance between the time-limited monopoly granted to inventors, and the total benefits to society of the increased inventive activity. The stated objective of TRIPS reiterates this principle. It reads in full:

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.

TRIPS Article 7 (Objectives)

A number of developing countries, most recently India in a TRIPS Council paper (India 2000)⁷, have questioned whether this balance can be achieved under the present TRIPS text. India points in particular to the fact that the agreement allows very limited flexibility. Although Article 8 explicitly allows members to adopt measures "necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development", it is clear from the same article that such measures may in no case contradict any of the substantive provisions of the agreement.

India also notes that even the use of existing flexibility in TRIPS by developing countries, for example regarding the use of compulsory licensing, has repeatedly been questioned by developed country members. Similarly, India points out that the meaning of "limited exceptions to the exclusive rights conferred by a patent" allowed under Article 30, has been very narrowly interpreted by the Dispute Settlement Body.

India's conclusion is that if TRIPS is to fill the function of a trade agreement, and not "a means of enforcing private rights irrespective of their trade effects" it needs to be clarified that the objectives and principles contained in articles 7 and 8 take precedence over other provisions in the agreement, and not the other way around.

India's concerns appear to be very broadly shared among developing countries. At the heart of the matter is the question of the relation between strong IPR protection and economic development. Developing countries generally take the view, as expressed by Kenya in another recent TRIPS Council

⁷ Previously, several countries submitted papers in WTO General Council during the pre-Seattle discussions in 1999 (references in the Indian paper).

submission, that strong IPRs "do not by themselves lead to FDI, neither encourage technology transfer nor local innovation" (Kenya 2000).

Developed countries, in contrast, express very strong trust in the capacity of IPRs to generate economic growth in and by themselves. "There is a direct correlation", writes a high representative of the US Department of State, "between a country's protection of intellectual property – patents, copyrights, and trademarks – and its economic growth and development... The tide of technology is strong and capable of lifting all economies. But nations that fail to protect intellectual property will be left behind." (Eizenstat 1999)

While it is a correct observation that strong IPRs correlate with high economic development, this does not necessarily imply a causal relationship. As already mentioned, existing scientific data, although inconclusive, clearly tends to support the developing country view in this matter (UNCTAD, 1996; Correa, 2000).

It should also be noted that intergovernmental organisations with development mandates recently have begun to flag concern about overly strong IPR systems. A World Bank research paper concluded that the balance now institutionalised in industrialised country IPR systems "is tipped toward the interest of commercialized producers of knowledge – tipped past the point of optimality even for the community of interests that make up the industrialized country societies" (Finger & Schuler 1999). The 1998 World Development Report questioned the increasing use of IPRs to protect fundamental research tools and thus block competitors from entering the field (World Bank 1998). The 1999 UNDP Human Development Report likewise discussed the increasing privatisation of basic research, and concluded in no uncertain terms: "The relentless march of intellectual property rights needs to be stopped and questioned" (UNDP 1999).

REVIEW PROCEDURES

There has been considerable disagreement between developing and developed countries over the built-in review provisions in TRIPS, in particular the review of subparagraph 27.3(b) on limits to life patenting, mandated to take place in 1999. During most of 1999 and into 2000, developed countries insisted that the review should only concern implementation of the subparagraph, while developing countries insisted it should concern the substance of the text.

While it is true that the term 'review' is used incoherently for several different purposes in the TRIPS text, and interpretation sometimes may legitimately differ, this is hardly true in this context. The text clearly says: "The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."

By mid-2000, however, all parties seemed to have agreed that the review will concern the substance of the subparagraph, and discussions finally got underway in TRIPS Council based on several written submissions. Due to the delay, however, this review now coincides with the first biannual review of the whole agreement, mandated for 2000, and the two discussions seem partly to be mixing into each other.

IMPLEMENTATION DEADLINES

The extended implementation deadline for developing countries (with the exception of LDCs) expired 1 January 2000. By this date, they were required to fulfil all parts of the agreement save implementation of product patents in those areas (mainly pharmaceuticals) where many countries previously only granted process patents.

Only a small minority of developing countries had fully implemented the TRIPS provisions by this date. According to a survey looking only at the life patenting clause, some 70 percent of all developing countries were still to complete implementation, and an even higher proportion in Asia and Africa (GRAIN 2000a). There is probably a wide variety of reasons, ranging from the technical difficulty and financial burden of the tasks at hand, to the complicated domestic political processes with many different stakeholders involved. It seems fair to conclude that the deadline was unrealistically short to begin with.

Regarding the life patenting provisions, there is also an unfortunate timing problem caused by the delay in the review scheduled for 1999. It now takes place after the implementation deadline instead of before, as foreseen by the agreement. This means that should any changes to the text result from the review procedure, countries may find themselves forced to revise a legislation they have just developed. For this reason, the African group proposed already in 1999 that the implementation deadline for subparagraph 27.3(b) be extended to five years after the conclusion of the review (Africa 1999).

NON-VIOLATION COMPLAINTS

Non-violation complaints are a peculiar feature of the GATT agreement. Under its general rules of procedure, a member is entitled to lodge a complaint against another member even though that other member has not violated the agreement in any way. If a member judges that benefits which should have resulted from the agreement are not forthcoming, and that the responsibility in some way falls to another member, this is sufficient basis for a complaint. If accepted by the dispute settlement mechanism, a non-violation complaint can be the basis for cross-retaliation measures like any other complaint.

In principle, GATT rules apply to TRIPS in this respect. However, a 5-year moratorium on non-violation complaints was agreed during the negotiation. This period ended 1 January 2000. A decision on whether to prolong or eliminate it was supposed to have been taken at the Seattle Ministerial. Developing countries, with support from a growing number of developed countries, insist that non-violation complaints should not be allowed in TRIPS, because of the fundamental difference between traditional trade agreements, which are about reducing barriers, and TRIPS which is a minimum standards agreement. The USA however defends the use of non-violation complaints in TRIPS, although it has also indicated that for the time being, it will lodge complaints regarding TRIPS based on violations only.

HUMAN RIGHTS COMPLIANCE

The right to protect intellectual property is a human right which has been set down in article 27, §2 of the Universal Declaration of Human Rights and article 15, §1c) of the International Covenant on Economic, Social and Cultural Rights. This human right is subject to limitations in the public interest, and it must be judiciously balanced not to infringe on other basic human rights.

Developing countries have raised concerns regarding actual and potential conflicts between the implementation of the TRIPS Agreement and the realisation of basic economic, social and cultural human rights. Specific concerns have been raised regarding the patenting of life forms, which is regarded by many developing and least developed countries as violating basic human values. The Africa group has requested the TRIPS council to exclude the patentability of life forms on the grounds that it is unethical, and the LDC group made a similar proposal in WTO General Council during the preparatory process for the Seattle Ministerial.

The UN Commission on Human Rights, Sub-Commission on the Promotion and Protection of human rights has noted these concerns (UNCHR, 2000). In particular, the sub-commission has pointed out possible negative consequences related to:

- patenting of genetically modified organisms and plant variety protection and the right to food;
- reduction of indigenous and local communities' control over their own genetic and natural resources and cultural values, and
- patented pharmaceuticals, restrictions on access to essential drugs and the implications for the enjoyment of the right to health.

The sub-commission on the promotion and protection of human rights has pointed out that "there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other" (ibid.). Reminding all governments of the primacy of human rights obligations over economic policies and agreements, the sub-commission has requested the TRIPS Council "to take fully into account the existing State obligations under international human rights instruments". The sub-commission has also requested and recommended further work by a number of international bodies, including WIPO, WHO, UNDP, UNCTAD, UNEP and UNHCHR, to clarify the relationship between intellectual property rights and human rights.

BILATERAL PRESSURES TO OVERCOMPLY

In the course of preparation of this report, we have been alerted to a considerable number of cases where bilateral trade pressures have been applied by developed countries to make developing countries legislate 'TRIPS-plus' levels of IPR protection or to implement various TRIPS provisions ahead of time. In the nature of the matter, those cases are usually not documented, nor have we made any efforts to substantiate or double-check facts, something which would at any rate be near impossible.

Given the large number of well-placed informants from national governments as well as intergovernmental and non-governmental organisations, we are left with the impression that there is a sizeable problem. The few literature mentions we have seen underscore this impression. Correa (1999) claims developing countries are "under the continuous pressure of some countries (notably the United States) to grant a protection broader than required under the Agreement". At the end of 1999, the office of the US Trade Representative was reported to have "46 current actions against poor countries for using internationally accepted and WTO compliant measures such as compulsory licensing and parallel import to save lives" (ACT-UP 1999). The WHO has noted that "some countries, formally and informally, have reported such pressure not to include TRIPS-provisions intended to safeguard access to essential drugs in their national legislation" (WHO 1999). Reichman (1998) ascribes such "bullying tactics" ultimately to "powerful firms in the developed countries" which stand to lose some advantages if developing countries fully exploit the 'wobble room' left in implementation of TRIPS.

The USA, at least for domestic audiences, is relatively open about its intentions. A deputy US Trade Representative, speaking at a Congressional hearing, makes a point of how "we have pressed countries wherever possible to accelerate implementation of [TRIPS] provisions", and details a number of cases where the USTR in close cooperation with US industry has intervened directly to demand new legislation in developing countries or deliver threats of WTO dispute settlement proceedings (Fisher 1999).

While perhaps not technically in violation of TRIPS, this kind of activity certainly seems to be in contradiction of the spirit of the very first paragraph of the agreement, stating that

Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement... Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

TRIPS Article 1.1 (Nature and Scope of Obligations)

Even more worrisome, if correct, are reports that intergovernmental organisations involved in advising developing country governments on the implementation of TRIPS have misused their position to further their own agendas. Again, we have not ventured to check details, but we have been made aware of several instances where WIPO counselling is reported to have resulted in TRIPS-plus IPR legislation, and UPOV involvement has created the impression that Plant Breeders' Rights are necessary for compliance with the sui generis provision of TRIPS 27.3(b).

Concerns related to biodiversity and agriculture

PATENTS ON LIFE

The life patenting provisions in Article 27 are no doubt the part of TRIPS which has raised most serious concern among developing countries. This should come as no surprise, as patents on life may over time bring profound changes in the way biological resources are controlled and exploited. The potential effects are relatively more important for developing countries because agriculture and other natural resource based livelihoods are still a major part of their economies, but also because biodiversity is one of few areas where they have a comparative advantage which could form the basis of indigenous economic development.

It should also be noted that patents on living organisms continues to be a highly controversial subject in many developed countries as well. In the EU, the new directive passed on the matter in 1998 after more than 10 years of negotiation was immediately challenged in the European Court of Justice by two member states (ECJ case C-377/89). Only three members had fully implemented the directive by the official deadline in July 2000 (GRAIN, 2000d), and recently the German government announced its intention to demand a renegotiation.

A number of developing countries have tabled formal submissions in TRIPS Council regarding life patents, including the full African Group, the LDC Group, India, Brazil, Venezuela and several other Latin American countries. Their arguments center on the following issues:

- *Biopiracy*. Although not (yet) a formal legal term, biopiracy is a concept formed by direct analogy to the concept of copyright piracy, commonly used, including in the TRIPS agreement itself, to describe unlawful use of copyrighted materials. Biopiracy refers to the appropriation of biological resources through IPRs without proper agreement with its developers (concerning domesticated materials) and/or without proper consent by relevant government authorities as mandated by the Convention on Biological Diversity (concerning wild materials).

Biopiracy occurs mainly due to low standards of what is considered a 'novelty' or an 'invention' for the purpose of patent registration, or sometimes by lax interpretation. One key issue is what information examiners are required to consider when checking for novelty (so-called prior art). For example, under US patent law, there is no requirement to check non-written sources outside the USA itself. This means that traditional use anywhere else in the world which is not documented in writing does not formally constitute prior art. A number of highly publicised cases of biopiracy have resulted from this rule, including the neem patent which the Indian government challenged in a US court⁸. But even in countries where examiners are in principle required to check both written and non-written sources globally, examination is in practice often limited to what is readily available in scientific literature and patent databases.

Another key issue is how the boundary between invention and discovery is drawn. Especially when the subject matter of a patent is a biological substance found in nature, such as a DNA sequence or a cell line, the dividing line tends to be blurred. A number of biopiracy cases involve this type of material, collected from developing countries and subsequently patented in developed countries.

⁸ And finally won, but only because written documentation could be identified in an ancient Ayurvedic document. For a recent update on this and a number of other representative biopiracy cases, see GRAIN (2000c).

Although most countries formally provide patents only for inventions (the USA being the main exception), the requirements for technical intervention (inventive step) are in practice often set at a very low level. Major controversy has surrounded the US practice of granting patents on isolated DNA sequences per se, but other developed country governments have only marginally higher standards. For example, under the EU biopatent directive, a biological discovery (for example a DNA sequence) becomes a patentable invention as soon as a potential use can be described.

It should be emphasized that TRIPS is certainly not the cause of biopiracy. As should be clear from the above, the space for biopiracy is created by deficiencies in national patent legislation. The concern raised by developing countries is that TRIPS in no way addresses this situation. In contrast to its very detailed requirements in many other areas, TRIPS leaves the definition of the three fundamental patent criteria (novelty, inventive step, industrial applicability) entirely to the discretion of national governments. No minimum standards are set. Implicitly, it can be argued, biopiracy is thus condoned by TRIPS.

In addition, it is not inconceivable that TRIPS may add insult to injury by forcing developing countries themselves to create laws to grant and enforce patents over biopirated objects. There is also a clear possibility that such patents may serve to block or circumscribe related R&D needing access to the same basic discovery or traditional technology.

For some developing countries, the risk of biopiracy is one of the arguments for excluding living organisms entirely from patent protection (eg Africa 1999, LDC 1999), thus removing the potential for biopiracy altogether. Others have suggested (e g India 2000a, Brazil 2000) that an international remedy to biopiracy should be sought by amendment to TRIPS. India notes that with patentability of life forms, this is the only practicable solution, as developing countries do not have the resources to monitor all piracy cases outside their borders and challenge them through litigation in foreign courts.

- *Ethical, religious and cultural values.* A fundamental opposition out of ethical principles to "the commodification and marketing of life structures" (Africa 2000) has been voiced by several developing country submissions. The very possibility of living organisms constituting inventions has been questioned. It has been pointed out that there is a clear difference between ownership of individual plants and animals, which is recognised in most cultures, and ownership of life-forms as such, which is not. But also some of the potential consequences of patents of life are questioned from an ethical point of view, such as privatised research increasingly targeting products for the affluent.
- *Right to save and exchange seed.* The right of farmers to save, reuse, exchange, or sell seed from their own harvests are restricted to various extents both by patents and by PBRs under the most recent UPOV text (1991). Of course these restrictions apply only to seeds protected under such systems. Any seed previously in the public domain will continue to be so. Yet it is quite likely that an increased use of IPRs on seeds would restrict developing country farmers' choices in many cases and increase their costs to the extent that it would directly impact on food security. As a rule, developing country farmers are dependent to some extent on the market for renewing their seed supply. Only in some areas and in a limited number of crops are there still intact local systems of traditional seed maintenance and farmer breeding which offer a complete alternative to commercial seeds. Typically, farmers rely on a combination of both systems, and thus the right to reuse and modify commercial seeds is key to the stability of their production systems.
- *Development objectives and control over research.* The general discussion mentioned above about the objectives of the agreement and the balance of interests has also been raised specifically in the context of life patents. The most recent African Group submission, for example, asks for the 27.3(b) review to address "whether and how intellectual property rights such as patents and plant breeders' rights lead to relocation of investment to natural resource endowed countries, transfer and

dissemination of technology, research and development, and innovation to developing countries" (Africa 2000). It also raises the issue about patents potentially restricting access to research materials.

The two major trends in agricultural research over the past 20 years have been the privatisation of previously public research, and the merging of the agricultural chemicals, plant breeding and pharmaceutical industries into what is now commonly referred to as the 'life industry'. The net result is that much of the research which was previously in the public domain, freely shared within the scientific community by means of peer-reviewed publications, is now held by private industry and shared under various forms of commercial agreements. After a rapid concentration process during the last few years, this industry is now dominated by only a handful of huge conglomerates. While the exact patterns of causes and effects are very difficult to analyse, it is clear that both the development of genetic engineering and the concomitant extension of the patent system to living organisms were two of the key factors driving this development. While originally much of biotechnology research took place in smaller, specialised research companies, these conglomerates now between them control most of it, with patents both on living organisms themselves and on associated knowledge and research tools as the primary means of control.

Consequently, access to patented processes, organisms and genes is now judged by most agricultural research organisations, private or public, as crucial to their long-term survival. An instructive example is provided by the recently established research partnership between the Swedish plant breeding company Svalöf Weibull (SW) and the German-based chemicals transnational BASF, which was negotiated strictly for this reason. SW ranked, before the deal, number 13 globally in plant breeding, so it was certainly not a minor company. Yet, SW's analysis was that without direct access to the patent stock of a considerably larger company, they would no longer be competitive. The issue was not the specific subject matter covered by BASF-held patents, it was accessing a large enough stock to be able to take part in the cross-licensing arrangements routinely made between the major players.

While already in full evidence in developed countries, the privatisation and concentration processes started later in developing countries. Relatively speaking, there is still more left of publicly funded and controlled plant breeding in the developing world, including that of national agricultural research and, importantly, that of the CGIAR international agricultural research centers. The CGIAR centers have traditionally had a strong policy of making their results freely available as "international public goods". Facing both increasing access restrictions and cases of biopiracy, many of the centers are now increasingly turning to patenting of their results. They are experiencing the exact same pressures as SW, and follow the same route of remedy, seeking arrangements with the large transnationals in order to ensure access to 'proprietary technologies'. This development is strongly encouraged by industry. In the words of a representative of Agrevo:

Patenting the results of their research will not prevent the Research Centres from making them available, but it will give them the option of entering into cross-licensing agreements or collaborations with companies holding other intellectual property of interest. Patents become bargaining chips which can be traded to further the research aims of the Research Centres.

(Richer 1999)

In practical terms, the result of the shift from public to proprietary science is plant breeding products incorporating dozens of different patents, restricting their use in agriculture and for further breeding. A current example, relevant to the developing country situation, is the so-called *GoldenRice*TM, a rice line genetically modified to express betakarotene (provitamin A). According to a "preliminary freedom-to-operate review" prepared by an industry-funded institute (Kryder et al 2000), this plant is covered by a total of approximately 70 different patents, of which between 0 and 44 will apply depending on the country of use, and require individual licensing agreements with each patent holder.⁹

⁹ In addition, there is the trademark protection, requiring that the name of the product be written exactly as above.

While developing countries have presented remarkably similar arguments in relation to article 27.3(b) in the TRIPS Council discussion, their concrete proposals regarding the limitations to life patenting vary considerably. At one extreme, Brazil and India accept in the main the present boundary drawn, but ask for clarification that only microorganisms in a strict scientific sense be patentable, and that more than simple isolation be required to fulfil the inventive step criterion.

At the other extreme, both the African group and the LDC group have proposed not only that the allowable exclusion be widened to all living organisms, but that it be made mandatory for all WTO members *not* to grant any patents on life, including microorganisms and all natural processes that produce living organisms.

SUI GENERIS PLANT VARIETY PROTECTION

The actual meaning of the obligation to provide sui generis protection for plant varieties has been intensively discussed. Developing countries have demanded clarification about what constitutes "an effective sui generis system". Several developed countries have noted that adopting UPOV-compliant PBRs is a way to fulfil the requirement, and even sometimes suggested that UPOV membership should be interpreted to be the content of the obligation.

However, the consensus now seems to be that countries are free to design sui generis protection provided they respect some basic IPR principles.¹⁰ A considerable number of WTO are planning to use this option, often adding other related elements of biodiversity legislation. Notably, the OAU has drafted and recently agreed a Model Law for Africa incorporating plant variety protection, biodiversity access and benefit sharing provisions in conformity with the CBD, and protection for biodiversity-related traditional knowledge (OAU 2000).

RELATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

The CBD objectives are the conservation of biodiversity, its sustainable use, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. While all three objectives may be relevant in this context, the third objective is the one most obviously linked to TRIPS, as IPRs are an important factor in influencing how benefits are shared.

The CBD contains several direct references to IPR protection. On the one hand, it notes that IPRs must be respected in implementing the CBD, for example in agreements on technology transfer. On the other hand, it recognises "that patents and other intellectual property rights may have an influence on the implementation of this Convention", and requires members to cooperate "in order to ensure that such rights are supportive of and do not run counter to its objectives" (CBD Article 16.5).

However, TRIPS does not contain any reciprocal reference to the CBD, and the question has been raised by a number of developing countries how it can be ensured that IPRs mandated under TRIPS will be supportive of CBD objectives, as required by their obligations to that convention.

A basic principle of the CBD is national sovereignty over genetic resources, and it specifically requires that another party can only access such resources subject to prior informed consent (PIC) and under conditions of benefit sharing on mutually agreed terms (MAT). Several developing countries have proposed amendments to TRIPS in order to clarify that patents covering biodiversity must also be subject to those principles. Most recently and comprehensively, Brazil has proposed that any such patent should include

- identification of sources of the genetic material

¹⁰ See Leskien & Flitner (1997) for a thorough analysis.

- identification of traditional knowledge used to obtain that material
- evidence of fair and equitable benefit sharing
- evidence of prior informed consent from the government or indigenous community for the exploitation of the subject matter of the patent (Brazil 2000).

Other countries have proposed that the conservation and sustainable use objectives of the CBD should also in some way be reflected in TRIPS.

RELATION TO THE INTERNATIONAL UNDERTAKING ON PLANT GENETIC RESOURCES

The International Undertaking on Plant Genetic Resources is a non-binding instrument negotiated at the FAO in the early 1980s as a framework for the conservation and sustainable use of (mainly) agricultural crop plants. In many ways a precursor to the CBD, the Undertaking is now in the process of being renegotiated to reflect the new international framework created by it.¹¹

The key component of the new Undertaking is foreseen to be a multilateral system for "facilitated access" to plant genetic resources of the major food crops. The system is conceived as a multilateral implementation of the CBD principles for access and benefit sharing, establishing, as it were, MAT and PIC collectively for the whole scope of the system.

The major advantage would be to avoid the immense transaction costs involved if agreements would have to be negotiated individually each time a plant breeder needed to access, for example, a foreign gene bank accession. Because intended to cover all genetic material within the major food crops, the Undertaking also holds the promise of recreating, within its coverage, the right of research access even to patented gene material, thus offering an alternative to the kind of byzantine maze of interrelated patents described above.

Negotiations have however been very difficult, and conflict between the "facilitated access" model and the IPR-based model of research cooperation has been a major cause. Breakdown has been very close on several occasions, most recently in November 2000 when the USA, together with Australia, Canada and New Zealand, refused to accept language they believed might conflict with certain provisions of TRIPS.

Some developing countries have suggested that TRIPS be amended to clarify its compatibility with the Undertaking.

TRADITIONAL KNOWLEDGE

As there is often a very strong link between biodiversity and the traditional knowledge (TK) about its conservation and use, the CBD explicitly acknowledges the need both to protect such knowledge and to promote its wider use. Again, TRIPS does not contain any corresponding provisions.

Over the last few years there has been increasing discussion both in CBD and WIPO fora about possible ways to provide better protection of traditional knowledge. Recently also UNCTAD convened an expert meeting on the issue, where two distinct approaches became quite clear¹². One, represented by WIPO and supported by many developed countries, primarily envisages protection by means of existing IPR systems and possibly new sui generis IPRs. The other, represented primarily by indigenous peoples organisations and supported by most developing countries and some UN

¹¹ For general background and a recent update on the negotiation, see GRAIN (2000b)

¹² The secretariat background paper (UNCTAD 2000) provides a good introduction to the issue. A large number of case studies will also be made available at <http://www.unctad.org>

organisations such as UNESCO, takes the view that existing customary law can in most cases be the basis for protection, supplemented as needed by national legislation, with IPR systems possibly an additional contribution in some cases.

In the TRIPS Council, many developing countries have proposed that TRIPS should in some way be amended to take TK into account to counter biopiracy, possibly by requiring patent offices to include it in examination searches.

GEOGRAPHICAL INDICATIONS

In a separate but partly related discussion, another agriculture-related IPR issue has attracted considerable interest from developing countries. Protection of geographical indications has traditionally been strong only in Europe. This is reflected in the fact that only wines and spirits, which represent the bulk of European 'appellations', are allowed the strongest form of protection which also bans expressions such as 'champagne-style'. Only for wines and spirits, also, is a multilateral registration system foreseen by TRIPS.

A number of developing countries are now considering the possibility of protecting as geographical indications some of their distinctive foods and other products, including some, such as basmati rice, which have been the subject of biopiracy. They are thus demanding that the higher level of protection should not only be available to wines and spirits, but opened up for general use.

Concerns related to pharmaceuticals

One-third of the world's population is estimated to lack access to pharmaceutical drugs (WHO, 1999). Barriers to drug access in developing countries are many, and they include poor health care infrastructure, irrational drug use and non-affordability of new drugs. Although intellectual property rights are probably not among the most important factors restricting drug access, serious concerns have been raised by several developing countries regarding potential negative implications of TRIPS on health care technologies and accessibility of drugs. With the adoption of the TRIPS Agreement around 50 countries, which had not previously conferred product patents to pharmaceuticals, were forced to do so (UNCTAD, 1997, in Correa, 2000b).

The World Health Organisation (WHO) shares some of these concerns, and WHO has become an active partner in supporting, facilitating and participating in discussions on the impacts of TRIPS on the accessibility of drugs in developing countries. WHO has also affirmed that it has an advocacy role to ensure that trade liberalisation contributes towards a more equitable distribution of economic benefits and a just society (Scholtz, 1999).

GENERAL EFFECTS OF PHARMACEUTICAL PATENTS

The pharmaceutical industry is increasingly global in scope. During the 1990's, there has been a wave of mergers and acquisitions of large pharmaceutical companies. Large national companies have become transnational (including the now part-Swedish Pharmacia & Upjohn and Astra Zeneca).

In most developing countries, including Sub-saharan Africa, transnational companies dominate the local market. A few large developing countries, including Chile, Argentina, India and China, have been able to stimulate the development of local pharmaceutical industries, which mainly produce generic drugs, often at a fraction of the cost of the original drugs. The generic drug industries are dependent on the possibility to copy original drugs, either (previously) in the absence of national patents on pharmaceutical products, by marketing generic versions after the expiration of patents, or by voluntary or compulsory licensing (see below).

Local manufacturing of drugs in India

The Indian pharmaceutical industry has a yearly turnover of US\$ 3 billion (Gerster, 2000). It employs around 500 000 employees in roughly 20 000 firms. An additional 2,5 million people are employed in the pre- and post-production sector. Drug prices in India are much below world average, and they have risen much less than the general price index in India over the last 15 years. For example, malaria treatment with the drug Lariam costs \$37 in the US and \$4 in India; the AIDS treatment AZT costs \$239 per month in the US and \$48 in India (Ford and Berman, 1999).

The development of India's pharmaceutical industry has been enabled by the patent law of 1970, which includes rights to process patents with 7 years protection for pharmaceuticals, but which has not allowed product patents. In addition, the law has allowed for compulsory licences granted by the state, in cases where a patent holder has not granted voluntary licences on fair conditions. India will have to apply the TRIPS rules for medical drugs at the latest by 1 January 2005, and some of the necessary changes have been made in the new patent law of 1999. The Indian pharmaceutical industry is concerned that TRIPS compliance will have considerable negative effects. Mr Israni, president of the Indian Drug Manufacturers' Association recently said in an interview: "Indian producers are being pushed out of the market and multinationals are going to dominate the market with far higher prices" (Gerster, 2000).

Concurrent with the recent wave of mergers of pharmaceuticals, inter-firm competition has hardened and has involved on the one hand the issuing of broad patents and secondary patents in attempts to secure continued access to and expansion of market shares. On the other hand, it has involved numerous challenges of pharmaceutical patents and patent infringements by competitors. Smaller firms in developing countries seldom have the resources to undertake litigation against such challenges. Developing country representatives have cautioned that as a consequence, generic firms may be forced out of the market. During this study, we have been alerted that this has started to happen.

Linked to this development is the concern that a higher proportion of patented drugs will lead to higher drug prices, with adverse impact on access to essential drugs and on public health. As noted earlier in this study, many developing countries have little faith in the ability of IPRs to encourage technology transfer and foreign direct investment, either in general or in the pharmaceutical sector.

One study has been done in Thailand by the WHO collaborating centre for health and economics (Supakankunti et al., 1999) on the impact on the pharmaceutical industry of the 1992 patent law revision, which essentially followed TRIPS requirements. The authors found that:

- there had been no significant increase in transfer of technology or foreign direct investment (FDI);
- originator pharmaceutical firms had done better than domestic generic pharmaceutical firms;
- the relative shares of the original drug market and the generic drug market had changed from being roughly equal (47,5%/52,5%) in 1992 to a situation in 1997 with original drugs having two thirds of the market share;
- pharmaceutical spending had increased at a higher rate than overall health care spending, i.e. drugs had become more expensive both in absolute and relative terms.

A study has also been done on the TRIPS implications for local production and access to medicines in Brazil (Bermudez et al., 2000). This study reviewed the first two years of the new Industrial Property Act. The Brazilian study revealed *inter alia* that:

- Of the drug patent applications filed since 1996, when the new Brazilian Industrial Property Act was signed into law, only 36 of 1387 patent applications were filed by residents of Brazil, or 2,6% of the total. 510 of the patent applications were by US residents.
- While Brazil's total imports for the period 1995 - 1998 increased slightly under 16%, the pharmaceutical imports during the same period increased over 228%.

The study concluded that "the greatest beneficiaries of recent changes in Brazilian legislation and the implementation of the World Trade Organisation's TRIPS Agreement have not been Brazilian companies or institutions, but transnational companies..." (Bermudez et al., 2000).

While it may still be too early to draw any firm conclusions, both studies, which are the first of their kind, support concerns raised by developing countries as regards impacts on FDI and transfer of technology.

Perhaps the most serious concern raised by developing country representatives is that stronger IPR on pharmaceuticals will not stimulate research and development of essential medical technologies.

In fact, while research and development of new drugs is intensive, R&D targeting diseases found in developing countries has practically come to a halt since the 1970s ('t Houen, 2000). Between 1975 and 1997, only 13 of 1223 new chemical entities, or 1%, were for the treatment of tropical diseases.

The World Health Organisation (WHO) has stressed the need to create mechanisms and incentives that drive research and development in the pharmaceutical field, since "market forces in pharmaceuticals are imperfect to meet therapeutic needs". One such mechanism proposed by the WHO is non-exclusive licensing of innovations and patents created with public funds in order to encourage competition and promote affordability (WHO, 1999).

PROPOSED EXCEPTIONS FOR ESSENTIAL DRUGS

Venezuela, Kenya and Pakistan have proposed that the exceptions to patentability in Article 27.3 (b) be extended to include the WHO Essential Drug List, in order to develop the principles established in TRIPS Article 8, i.e.:

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition ...

Essential drugs are defined as drugs "that satisfy the health needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage form". The first WHO Model Essential Drugs List (EDL) was published 1977. WHO's EDL serves as a model for the development of national essential drugs lists, and it is a key strategy to help improve access to essential drugs. Over 140 countries have adopted the use of essential drugs lists. The current WHO Model EDL contains 306 drugs. Of these, around 15 are patented and the rest are generic drugs.

WHO has commented to the proposal by Venezuela, Kenya and Pakistan that since both the implementation of TRIPS and national essential drug lists are developed through national legislation (WHO, 1999), WHO recommends using the options available in TRIPS at the national level rather than making a universal exception for essential drugs which may not be adapted to the individual needs of all developing countries.

WHO has also remarked that since the current process within WHO to update the model Essential Drugs List has cost as a criterion for selection of drugs for the list, vital and lifesaving drugs are sometimes not classified as essential by the WHO expert panel due to their high cost. According to WHO, excluding WHO Model Essential Drugs from patentability is therefore potentially flawed, i.e. it would not significantly assist developing countries in increasing their access to essential drugs.

'WIGGLE ROOM' ISSUES

As discussed above, there is widespread concern both in developing country governments and in intergovernmental organisations (notably the World Bank and UNDP) regarding the achievement of a balance of interests between inventors' interests and the benefits of society under the present TRIPS text. In part, the balance achieved may depend on the effective 'wobble room' in TRIPS to allow national legislation for individual countries' needs. Some of this room is given by provision in TRIPS Article 30 for exceptions to exclusive rights.

All national patent laws allow for exceptions to the exclusive rights granted by a patent. TRIPS Article 30 provides for such exceptions to exclusive rights, and it does so in general terms, leaving member states certain freedom to define exceptions to exclusive rights in their national legislation. At the same time, since TRIPS only provides for exceptions in general terms, any exceptions may be challenged by other members before WTO dispute settlement tribunals.

The exceptions most relevant for pharmaceuticals are experimental use, early working and parallel imports. In addition, TRIPS article 31 allows compulsory licensing.

Experimental use

Many developed countries allow further innovation on an invention without the consent of the patent holder. TRIPS article 30 may be interpreted to allow such experimental use, and this option may possibly assist in stimulating R&D in developing countries by permitting further improvement of patented drugs.

Early working

Another exception which has been confirmed by a WTO panel to be compatible with TRIPS article 30 is the 'early working' exception, or allowing use of a patented product before the expiry of the patent for development of a generic alternative, to enable it to be put on the market immediately after the expiration of the patent (WTO, 2000b). Generic competition will lower consumer prices, so early availability of generics is clearly in the interest of developing countries' strategies to increase affordability of drugs. WHO supports the use of early working exceptions by developing countries (Scholtz, 1999).

Parallel imports

Parallel import is the importation of drugs to one country from another where the patent holder sells the same drug at a lower price. Parallel imports are widely used by many countries to bring down drug costs.

The legal basis for allowing parallel imports is that the inventor is judged to have exhausted his/her rights through the first sale of the product, and he/she has no right to control any further resale of the invention. TRIPS article 6 states that the Agreement is silent on the issue of exhaustion of intellectual property rights, which may be interpreted that it hence leaves to national legislation to determine whether or not parallel import is permitted.

Parallel imports could be one of the tools of developing countries to provide affordable drugs (South Centre, 1997, Correa, 2000b, 't Hoen, 2000). The WHO supports the use of parallel imports to increase access to essential drugs (WHO, 1999).

It has been argued that parallel imports would discourage pharmaceutical companies from introducing lower prices on drugs in developing countries, since these could then be re-imported by developed countries at developing country prices. However, the regulation of parallel imports is an issue for the importing and not the exporting country (Correa, 2000b). Hence, if developing countries allow parallel imports in their legislation, developed countries could treat parallel imports differently, and measures could be taken to ensure that the lower prices are valid only in developing countries.

In fact, GATT principles may be interpreted to not only support but actually require the possibility of parallel imports. According to GATT 1947, Article III.4., countries must treat imported products no less favourable than products of national origin. The logical interpretation of this and other provisions is that GATT in fact *requires* WTO members not to forbid parallel imports (Correa, 2000b).

Compulsory licensing

TRIPS article 31 allows compulsory licensing, or "use without the authorization of the right holder" when efforts to obtain such authorization have been made but have not been successful within a "reasonable period of time". The right holder must be compensated for the license, and a number of other conditions also apply.

Most countries allow some form of compulsory licensing, which is one of the major mechanisms that can be made available to promote competition and increase access to affordable drugs. WHO supports the use of compulsory licenses to ensure that drug prices are consistent with local purchasing power and hence safeguard public health interests. However, to date the real 'wobble room' for development countries to use compulsory licences remains uncertain.

The use of compulsory licenses has been opposed by the pharmaceutical industry, on the grounds that they may threaten cost recovery for development of new drugs and hence discourage investment and R&D. The use of compulsory licensing and parallel imports to protect public health in developing countries has also been challenged by e.g. the USA, although over a hundred compulsory licenses

have been granted in the USA to remedy anti-competitive practices and for governmental use, including national emergencies.

US pressure against low cost AIDS drugs in Thailand and South Africa

”In 1993, under US urging, **Thailand** adopted a law banning parallel imports, which allow the importation of drugs to one country from another where the patent holder sells the identical drug at a lower price. Parallel imports are widely used by many countries, including the United Kingdom and the Netherlands, to bring down the cost of drug therapies.

Trade pressure against Thailand was most recently stimulated by the government's attempt to begin producing the anti-HIV drug ddI. The government was planning to offer people with AIDS at least one low-tech double therapy combination (AZT/ddI) at an affordable price. Currently, ddI is exclusively marketed by Bristol-Myers Squibb at a monthly cost of \$166. Since July, 1997 the daily minimum wage in Thailand has been frozen at \$4.50.

Thailand dropped its ddI plan when it was threatened with trade sanctions on some of its key exports. This threat came at a time when the Thai economy was reeling from the widespread South East Asian financial crisis. Thai physicians and patients were particularly outraged when they discovered that ddI was invented by the US government and is licensed on an exclusive basis to the US drug manufacturer Bristol-Myers Squibb.

In addition, last summer the US stimulated a Thai legislative bill, expected to be signed into law soon, that severely restricts the use of compulsory licenses. Under the urging of US trade officials, Thailand will implement a law that is much more restrictive than the rules set out in the TRIPS agreement, the internationally accepted standard.” (Ford & Berman, 1999)

The current AIDS tragedy in Thailand is illustrated by the situation at Bamrasnaradura hospital in Bangkok, where only 20 out of 2000 aids patients who seek treatment each month can afford the triple drug cocktails that have become standard in developed countries.

South Africa's draft Medicines law includes provisions for the Ministry of Health to authorize the ”supply of more affordable medicines in certain circumstances so as to protect the health of the public”. One of the bases for these provisions is the catastrophic AIDS situation in the country. An estimated 20% of South Africans are infected with HIV (Mutume, 2000). Of these, a very minor portion has access to AIDS drugs.

The provision of parallel imports and compulsory licensing in South Africa's patent legislation was thus limited to medicines, and it was subject to decision by the Ministry of Health under certain circumstances. Despite these limitations, the South African law was challenged by 42 pharmaceutical companies. The US government imposed sanctions against South Africa, and development cooperation was conditioned on the withdrawal of the provisions (’t Hoen, 2000). Pressure also came from the European Union (Loewenson, 2000).

After a global NGO campaign, in which activists from the USA, Africa and Asia opposed the US government's sanctions, these were eventually lifted. The US government has now offered African nations a \$ 1 billion loan (at commercial interest rates) to import AIDS drugs from the US. The pharmaceutical companies temporarily suspended their judicial action against the South African draft law. Five pharmaceutical companies offered to provide AIDS drugs at 60 – 85% off the price charged in the US or Europe (Loewenson, 2000).

However, it has been estimated that even with discounts of up to 90%, the drugs being offered by the western pharmaceutical companies would still be up to 10 times more expensive than the cheapest generic alternatives (Mutume, 2000).

PROTECTION OF UNDISCLOSED INFORMATION

While patents grant temporary monopolies to inventors, the inventor is in exchange obliged to give full public disclosure of the invention. An inventor may instead choose to protect an invention by

keeping information about it secret. Trade secrets are protected in most developed country legislations. In this case, there is no registered exclusive right involved.

In article 39.3, TRIPS requires its members to protect the secrecy of data which is submitted for approval of new pharmaceutical or agrochemical products. The US and the EU members at present provide several years of data exclusivity for regulatory approval of pharmaceuticals. In EU, this provision was initially introduced to compensate for the lack of patent protection at the time in Spain and Portugal. These countries now have patent protection of pharmaceuticals, and the data exclusivity rights hence confer a form of additional protection, which is clearly advantageous for pharmaceutical companies, but which seems to contradict the basic principles of unfair competition law. According to these, protection should be given against dishonest commercial practices or the unfair commercial use of undisclosed information, but this does not mean to grant exclusivity (Correa, 2000b). By preventing that subsequent applicants rely on data submitted for approval of pharmaceuticals, development of generic drugs and drugs under compulsory licensing will not be possible without the replication of time-consuming and expensive clinical trials to establish the efficacy and safety of the drugs.

The requirement in TRIPS article 39.3 has no parallel in earlier international IPR treaties. Its introduction into TRIPS was directly in the interest of the pharmaceutical and agrochemical industry. What was previously, at least in Europe, a complement to ensure protection in the absence of patent rights has become a universal standard which confers double protection of both patent rights and trade secrets for the same product.

In bilateral trade actions, the US government has argued that member countries are obligated by TRIPS article 39.3 to prevent generic drug companies from even relying upon published scientific papers without permission (Correa, 2000b).

Public health groups have proposed that the US and EU rules on data exclusivity be changed. Médecins sans Frontières, Health Action International and Consumer Project on Technology have urged WTO member countries to communicate to WTO the need to avoid excessive and anti-competitive levels of data exclusivity, and has asked WHO to provide the WTO with a report on the least trade-restrictive policies with regard to such data.

TRADITIONAL MEDICINE

Traditional medicine – medicine based on natural products and indigenous or local knowledge – is of major importance in many developing countries. It has been estimated that 80% of the world's population is dependent on or uses traditional medicine (the Crucible Group, 2000). While much of the traditional medicine use remains in the informal sector, there is also a large formal market for traditional medicine in many developing countries. For example, the study on TRIPS and access to drugs in Thailand (see above) noted that 19,4 % of the drug stores in Thailand are licensed to sell only traditional medicines.

In relation to TRIPS, developing countries have raised concerns that attempts to patent indigenous system of medicine, knowledge of medicinal plants and food crops could affect public health. Possible negative impacts could arise e.g. by patents themselves restricting traditional use or by having the indirect effect of discouraging knowledge holders from disclosure of traditional knowledge for purposes of improvement of local health practices. On the other hand, there is also a need to protect indigenous and traditional knowledge, and as noted above efforts have been made to find room in the TRIPS agreement to do this.

Interestingly, there has been resistance both within WIPO and from member states, notably the USA, against the idea of adapting IPRs for traditional knowledge.

An illustration of the sensitivities involved is the US reaction to a Thai government proposal in 1997 to introduce a new system of registration for medicinal genetic resources and traditional healers' knowledge. Even before the draft had become public, the Thai patent office director received a very

aggressively worded letter from the US ambassador claiming that such a proposal could constitute a violation of the TRIPS agreement (Pollard, 1997).

Sida's activities related to TRIPS

A number of current Sida-funded activities are related to or impacted by TRIPS. This chapter, based on input from staff in various Sida departments, highlights some of these activities.

Support to capacity building in developing countries

The examples of Sida-supported activities provided here illustrate Sida's ongoing support to further the understanding of implications of TRIPS in developing countries.

AFRICAN CENTRE FOR TECHNOLOGY STUDIES (ACTS)

African Centre for Technology Studies (ACTS), based in Kenya, started in 1988. The main objective is to further the development of African perspectives and capacity in areas related to biotechnology, biodiversity and biopolicy. ACTS runs policy research projects, educates decision makers and negotiators and arranges conferences around different themes. Currently, ACTS' work is focused on support to African WTO members working to implement the obligations in the TRIPS agreement. Particular focus is on TRIPS article 27.3 b, access to genetic resources, 'Farmers' rights' and Material Transfer Agreements.

CRUCIBLE II

The 'Crucible Group' was formed 1992 and currently consists of around 45 people from the private sector, the scientific community, donor agencies, indigenous people and NGOs, which in their personal capacities work with policy analysis across FAO/CBD/WTO/UPOV/WIPO/WHO on issues related to access to genetic resources, protection of biological innovations and/or traditional knowledge. The Crucible group writes joint policy analyses and aim at coherent recommendations to decision makers and negotiators in the fora mentioned above. The group has developed annotated model legislation related to access to genetic material, innovation and protection of traditional and indigenous knowledge, aiming to assist developing countries' positioning in relation to TRIPS and the revision of TRIPS article 27.3 b.

A background policy analysis 'Seeding Solutions' was published in 2000. The annotated model legislation is planned for publication spring 2001. Sida provides support to Crucible II by funding and by participation in the Crucible process since 1992 by Carl-Gustaf Thornström, SAREC.

Support to NGOs

Sida is supporting a number of NGOs working on TRIPS related issues. Three of these NGOs are Third World Network (TWN), Genetic Resources Action International (GRAIN) and the Swedish Society for Nature Conservation (SSNC).

GRAIN

GRAIN has received support from Sida since the late 1980's. GRAIN will focus on the following activities in the coming years:

- Monitor, research and provide analytical information support on the expansion of IPRs and related rights regimes through international instruments and bodies
- Sustain the production of current information tools on IPRs (such as the listserver BIO-IPR) to service those active at the national and international levels with up-to-date information and analysis.
- Participate in joint activities with national NGOs and others working to counter IPRs on life and promote community rights.
- Respond positively to requests for capacity building support on these issues where needed.
- Collaborate with groups in the regions to better articulate community rights, document cases, and share information across countries and continents.

THIRD WORLD NETWORK (TWN)

The biodiversity and biosafety programme by TWN year 2000-2002 supported by Sida focuses on the following work related to TRIPS:

- Research on appropriate models and forms of access and benefit-sharing arrangements (including policies and laws) for developing countries at national level, and advice to policy makers in developing countries in developing such national policies and laws.
- Research on appropriate arrangements at the international level (particularly the Biodiversity Convention and the International Undertaking) that would assist developing countries to achieve the goals of equitable benefit-sharing, and assisting developing countries in the negotiations.
- Monitoring trends in IPR regimes and practices at national, regional and international levels, and analysing such trends for their potential effects on the goals of equitable benefit sharing and biodiversity conservation and use.
- Research into existing and evolving international IPR regimes and providing suggestions on possible options in implementing such regimes at national level, as well as in the review and possible reform of such regimes, to make them more in line with the principles of equitable benefit-sharing and the conservation and use of biodiversity.

The above includes development of research and negotiating capacity of developing countries to bring forward their case and concrete proposals in various relevant international fora. The programme therefore includes a strong element of training, workshops and capacity-building activities.

SWEDISH SOCIETY FOR NATURE CONSERVATION (SSNC)

Sida's support to SSNC's International Program is largely focused on a co-operation with NGOs in Asia, Africa and Latin America. Some of these organisations are actively involved in TRIPS-related issues.

SSNC works actively to increase the understanding of TRIPS, for example through an information campaign in Sweden before Seattle, where SSNC together with five other Swedish NGOs initiated a dialogue with the Swedish Minister for International Trade to present their views on Swedish government positions for the upcoming WTO ministerial meeting in Seattle. The major message from SSNC and the other organisations related to TRIPS was the following:

the WTO's TRIPS agreement deals with areas where different social structures and perspectives between countries in the North and South present great challenges for the negotiators. It is of great importance that Sweden takes the lead and shows that it is prepared to listen carefully to the South's argument.

The stipulated period of transition for developing countries has been very short when you consider the challenge involved in creating legislation for intellectual property rights for genetic resources that are adapted to the conditions in the countries, and guaranteeing protection for the local community's knowledge and resource base.

Before we can demand that developing countries implement TRIPS 27.3(b) in its present form, more research is necessary on what effects the patenting of genetic resources may have on biological diversity, on relations between North and South, and on global food security.

Through this kind of action SSNC is opening a dialogue with the Swedish government for better understanding of relations between the North and the South.

Support to workshops and training

AFRICAN REGIONAL WORKSHOP ON IMPLICATIONS OF INTERNATIONAL INSTRUMENTS ON SUSTAINABLE MANAGEMENT OF BIODIVERSITY

In January 1999 Sida supported an African Regional Workshop on Implications of International Instruments on Sustainable Management of Biodiversity through GRAIN, by SADC Plant Genetic Resources Centre (SPGRC) and the Southern African Traditional Leaders Council for the Management of Natural Resources (SATLC) with the objective to develop long-term strategies with regard to international agreements affecting biological diversity and peoples rights. Participants included government negotiators, non-governmental organisations (NGOs) and peoples organisations (POs) from Southern African countries. The objectives where:

- To bring together African negotiators (to the CBD, FAO, WTO, etc.) together with lawyers, researchers and representatives from NGOs and POs.
- To develop long-term strategies with regard to the implementation of CBD and FAO commitments, especially collective rights.
- To develop strategies and common position, in preparation for the TRIPs review.
- To look at ways to co-ordinate future regional activities and information sharing on cultural and biodiversity related issues.
- To host a three-day legal training specifically for lawyers on international law.

One outcome of the meeting was the subsequent development of an African Model Legislation for the Recognition and Protection of Rights of Local Communities, Farmers and Breeders and the Regulation of Access to Biological Resources. The Model Law was developed to respond to:

- the possibility stated in TRIPS for countries to develop a sui-generis (alternative) system to patent.
- the Convention on Biological Diversity's objectives of conservation, sustainable use and fair and equitable sharing of the benefits arising from the utilisation of genetic resources.
- The "Farmers Rights" which is one of the points for discussion under FAOs International Undertaking on Plant Genetic Resources.

THE URUGUAY ROUND AND FUTURE NEGOTIATIONS RELATED TO AGRICULTURE

FAO is making efforts to assist developing countries in their Uruguay Round follow-up process. This is done through training programs in five regions. The training focuses on current WTO agreements and their implications for agriculture and trade, emerging issues and topics relevant to future negotiations. Improved knowledge of TRIPS and its consequences is an important component in the training program. Sida gives financial support to training of key personnel from the African region.

The target audience of the training programme comprises of policy analysts as well as technical specialists in relevant ministries, including the private sector and academic institutions.

DIALOGUES ORGANISED BY ICTSD/QUAKER UNITED NATIONS OFFICE

To strengthen developing countries' ability to understand the options for advancing their public policy objectives through the implementation or review of the TRIPs Agreement, International Centre for Trade and Sustainable Development (ICTSD) together with the Quaker United Nations Office in Geneva and the Quaker Peace & Services in London will arrange five Regional Multi-stakeholder Dialogues. Summaries of debates drafted by organisers in co-operation with participants will feed back into an ongoing Geneva-based process aimed at facilitating consensus building and creative thinking for the review of TRIPs.

Support with potential TRIPs / CBD implications

Below are four examples of current Sida-supported activities, where there are potential implications and outstanding questions as regards transfer of genetic material, IPR claims by third parties, protection of traditional knowledge etc., in relation to TRIPs and/or CBD.

THE CONSULTATIVE GROUP ON INTERNATIONAL AGRICULTURAL RESEARCH (CGIAR)

Sida provides core support to international agricultural research institutes within The Consultative Group on International Agricultural Research (CGIAR). Support is also provided to increased Swedish research cooperation with the CGIAR institutes. CGIAR is a consortium of research institutes supported by 58 developing and developed countries, private foundations, regional and international organisations. The overall goal of CGIAR is to contribute to long term food security and poverty reduction in developing countries through research, research cooperation, capacity building and policy support, and through promotion of sustainable agriculture based on ecologically sound use of natural resources. FAO, UNDP and the World Bank are three co-sponsors of CGIAR. CGIAR's activities are carried out within a network of 16 international research institutes which work in accordance with a research agenda formulated by CGIAR. Most of the research institutes are located in developing countries.

In 1994, an agreement was signed between FAO and the 11 genebanks within CGIAR, which put the genetic material held in trust by the CGIAR institutes under the auspices of the FAO Commission on Genetic Resources for Food and Agriculture. Access to so-called 'designated germplasm' by third parties is regulated in detail. However, in relation to CBD, TRIPs and FAO/IU, several questions remain, e.g.:

- What inventive step is required when a third party utilises genetic material under the FAO/CGIAR agreement, and when IPR protection can be sought for the final product?
- The major part of CGIAR's mandate crops and CGIAR ex situ gene pools of these crops are proposed to be included in the multilateral system for access to genetic resources currently negotiated in FAO's International Undertaking. How will these gene pools be defined? Which components of 'designated germplasm' will be included, and what will be the mechanisms?

SADC PLANT GENETIC RESOURCES CENTRE (SPGRC)

SADC Plant Genetic Resources Centre (SPGRC) is a regional genebank and plant genetic resources centre servicing the 12 member countries of SADC in Southern Africa. SPGRC was started in 1988

with Nordic donor support, and in cooperation with the Nordic Gene Bank. The Nordic countries will provide long term support to SPGRC, at least 20 years. The main objective is to create ex situ-collections of plants of major economic importance in the region. The long term goal of SPGRC's activities is to contribute to long term food security and poverty reduction in the SADC countries.

After CBD, when national sovereignty of genetic resources was established, SPGRC has developed material transfer agreements which regulate depositions of national material at the regional SPGRC genebank in Lusaka, Zambia. The material transfer agreements also regulate how the genetic material may be utilised by third parties. With its experience in regulating transfer of plant genetic material across national borders in Africa, SPGRC has also been instrumental in the development of African model legislation on plant variety protection and protection of traditional knowledge.

Examples of problematic issues for SPGRC:

- How will SPGRC deal with applications for patents and/or plant variety protection by third parties (e.g. the international life industry corporations) on varieties based on genetic material which originate at SPGRC? What will be the inventive step required?
- the passport data of accessions sometimes contain ethnobotanical information, e.g. the medical uses/properties of a plant. This information is protected by the Convention on Biological Diversity (CBD) article 8j. How does SPGRC deal with sharing of benefits when this information is utilised by third parties?

ZAMSEED

Sida initiated support during the 1980's to collaboration between Svalöf AB and the new state-owned plant breeding company Zamseed in Zambia. The aim was development of local breeding and marketing of modern varieties of maize and other crops. Svalöf AB, later Svalöf-Weibull AB became part owner of Zamseed, which was later privatised. Some of the outstanding questions are:

- How is transfer of genetic material between Zamseed in Zambia and its part owner Svalöf-Weibull in Sweden regulated in accordance with e.g. CBD article 15 (which affirms the national sovereignty of genetic material)?
- What will be the long term implications for Zambia's food security if an increasing share of the country's crop genetic resources are commercialised and come under intellectual property protection?

BIOEARN

Sida supports BIOEARN, a programme for East Africa (Kenya, Ethiopia, Tanzania and Uganda) which aims at strengthening national and regional capacity within biotechnology, biosafety and biopolicy. Swedish research institutes in the area of biotechnology participate in the programme. The CBD requires fair and equitable sharing of benefits from the use of genetic resources. TRIPS requires minimum standards of IPR protection. This raises the following questions:

- What material transfer agreements are needed within BIOEARN's activities?
- How are breeders' exemptions and farmers' exemptions in relation to plant variety protection dealt with by BIOEARN?
- How is access by third parties regulated?
- How will benefit sharing be regulated if more than one country contributes with genetic components which lead to commercial products?

Conclusions and recommendations

General conclusions

NO SUBSTANTIAL BENEFITS FOR DEVELOPING COUNTRIES

The most obvious but also most central conclusion of this study is that the TRIPS agreement is not likely to bring any substantial benefits for developing countries.

By this, we are not saying that increased use of IPRs in developing countries will have no benefits. This is a much larger and more difficult question which we have not even attempted to answer. Our superficial literature review indicates that IPR experts are at a loss as well. Present scientific consensus appears to be that there may be benefits to be reaped, but that the potential is very unevenly distributed. In particular, little benefit is expected to flow to LDCs.

What we *are* saying is that imposing a *minimum standard* of IPR protection does not benefit developing countries. This is what TRIPS is about. The agreement does not create any new options which were not present before. All kinds of IPR protection were available for developing countries to use also before TRIPS.

The optimal IPR strategy for developing countries would very likely be the same one that developed countries used during their industrial development process. They built an IPR system gradually, implemented forms of protection tested by experience in other countries, adapted those to national requirements, created own sui generis forms when needed, and cooperated on a voluntary basis to achieve an increasing measure of international coordination.. This, however, is exactly the strategy that TRIPS does not allow. The minimum standard is already fixed at the present (high) level of protection in developed countries. The space for experimentation with levels and forms of protection which used to exist below that level is no longer available.

SUBSTANTIAL COSTS FOR DEVELOPING COUNTRIES

In addition, it is certain that implementing TRIPS will have substantial costs for developing countries, although the size of those costs is impossible to establish with any accuracy.

The direct costs of practical implementation are a known and quantifiable factor. Depending on the previous status of IPR protection the added cost will vary considerably between countries. Both in relative and absolute terms, the cost will tend to be highest for the poorest countries, where most is lacking both in terms of IPR legislation, administrative capacity and enforcement structures.

Another known but un-quantified factor is higher costs for imports of products and for access to technology. If the high expectations for economic benefits to developed countries (see below) are to be realised, there will have to be a substantial increase in prices for the products concerned in developing countries. While dynamic effects also in developing country economies have been predicted in the

longer term, these are much less certain than the immediate costs, and even at best there will be a considerable time lag before they compensate.

A largely unknown factor are the costs related to possible restrictions to economic development created by IPRs. In particular, because of its weight in developing country economies, any restriction to R&D in agriculture could have serious economic consequences. This might also be true for restrictions limiting use of farm-saved seed, and for restrictions limiting the production of generic drugs.

SUBSTANTIAL BENEFITS AND NO IMMEDIATE COSTS FOR DEVELOPED COUNTRIES

In contrast, large benefits are expected by developed countries, mainly in the form of increased IPR revenue for their companies in developing country markets. For example, the US copyrighted products industry has calculated their annual loss of revenue due to unlawful copying abroad to over 20 billion dollars (Fisher 1999). Even though such estimates may be inflated, and even if only a fraction of that revenue loss will eventually be recuperated under TRIPS enforcement, the global figures when all IPR forms and all developed countries are added up are still likely to be very substantial.

As TRIPS was designed to accommodate the present level of IPR protection in the major developed countries, there is also virtually no direct implementation cost.¹³

OWNERSHIP

Perhaps the most serious concern, raised by the previously quoted World Bank evaluation of the development implications of TRIPS (Finger & Schuler 1999), is that developing countries have no sense of ownership in the agreement.¹⁴ Developed countries, by contrast, exhibit a very strong sense of ownership.¹⁵

In essence, Finger and Schuler conclude, through TRIPS, the free rider problem originally identified "has been swapped for a *forced* rider problem... the advanced countries saying to the others, *Do it my way!*". In fact, as we have seen, they are also saying, *Do it for my sake!*. The likely effect of TRIPS in trade terms is a net flow of resources from developing to developed countries, at least in the short and medium time frame. In addition to these direct economic effects, there are the various concerns expressed about potential indirect, long term effects on the economy and development objectives, and about conflicts with non-economic values, especially in the field of life patenting.

All in all, it is an extremely unbalanced agreement. While it can possibly be enforced by strong-arm tactics, the wisdom of doing so must be seriously questioned in any perspective save the most narrow rent-seeking. TRIPS has arguably contributed its fair share to the present legitimacy crisis of the WTO. The need for overall confidence-building and process reform is widely acknowledged. In particular, the need to better integrate development concerns in WTO culture is obvious. As the conflicts over TRIPS by and large relate to development strategies, it seems unlikely that a solution to the wider problems of the WTO can be reached without a reconsideration of TRIPS.

¹³ Warnings are heard, however, that there may be indirect costs in the longer term. "This high protectionist trend may backfire on the developed countries because the chronic state of overprotection to which it leads tends to misallocate scarce resources devoted to research and development and to reduce the efficiencies that flow from reverse engineering and from cumulative, sequential innovation generally." (Reichman 1998) See also the criticism of the balance of current IPR systems in industrial countries referred to on page 21.

¹⁴ This was amply confirmed by our conversations with developing country diplomats, sometimes in much less polite terms, e.g. "It was crammed down our throats".

¹⁵ For example, in the words of a deputy USTR: "[TRIPS] was an historic achievement: it required all WTO members to pass and enforce copyright, patent and trademark laws, and gave *us* a strong dispute settlement mechanism to protect *our rights*." (Fisher 1999, emphasis added).

INCREASE FLEXIBILITY

From a development perspective, it seems clear to us that what is needed in TRIPS is increased flexibility for developing countries to design IPR laws and decide on levels of protection.

We are aware that from certain other perspectives, this may not be an attractive proposition. It is quite likely that some modifications to TRIPS which are desirable from a development perspective will conflict with the interests of developed country export industries. Our terms of reference, however, have been to analyse TRIPS from the perspective of developing country interests and from the policy objectives of Swedish international development cooperation. This is the basis on which our conclusions are drawn.

It may well be that other interests on balance should carry more weight in Swedish trade policy. As evident from the content of this report, we have not addressed this question, nor have we attempted to balance the different interests. It falls outside our remit. However, what we do feel confident in saying is that there are no substantial development-related arguments to defend the TRIPS agreement in its present form.

There are several options which would restore more or less of the flexibility in IPR legislation removed by TRIPS. We think all of them should be considered.

The most radical solution, but also in many ways the simplest, would be to repeal the whole agreement and revert to the previous system of IPR coordination by way of the separate intellectual property treaties administered by WIPO. This is less far-fetched than it may at first sound and it may in fact be very helpful to the WTO as an organisation.¹⁶ As widely recognised, TRIPS is a foreign element among the WTO agreements, prescribing minimum standards for domestic legislation, rather than setting maximum limits for trade barriers. Whether or not the WTO should continue to develop in this direction, becoming something which "might better be called the World Market Harmonization Organization" (Helleiner 2000) is one of the core issues causing its legitimacy crisis. Should the WTO be mandated to continue with minimum standards for labour legislation, environmental legislation, investment policies and any other policy area which in some way relates to trade (and there are few which don't). If so, then harmonisation of IPRs will fit well into the picture. If not, it would seem to be a better option to return IPR issues to their previous context at WIPO, with voluntary accession for countries to IPR treaties on a one-by-one basis. Most developing countries would likely not make radical changes in existing IPR legislation, except for the controversial new areas in life patents and pharmaceuticals.

A somewhat less radical option, but one which involves much more work for the WTO, is to renegotiate TRIPS on a less ambitious level, reducing commitments to clearly trade-related aspects.

Another possibility, which will no doubt surface in the discussion if and when a new round of negotiation gets underway, is to abandon the principle of the single undertaking.¹⁷ By making TRIPS and other new additions to the WTO framework optional for members an entirely different negotiating dynamic would be created. Each agreement would, as it were, be required to "sell" itself to the membership. Unless there was demonstrable mutual benefit, membership would stay limited, and the agreement largely ineffective.

¹⁶ We want to underline that this is not a proposal raised by any of the developing country missions we have spoken with, who were as a rule extremely loyal to the WTO treaties, despite serious grievances. However, our position as consultants does not require any such allegiance.

¹⁷ The "single undertaking" refers to the take-it-or-leave-it principle applied for the first time in the Uruguay negotiation. Membership in the WTO requires adherence to all the agreements without exception.

On the level of modifications and amendments to the existing text, a number of proposals have been made by developing countries.

Finally, as an absolute minimum, and something that should be self-evident, there is a need to clarify that developing country members have the right to use existing flexibility in the TRIPS without interference and over-compliance pressures from developed country members, in accordance with Article 1.

Recommendations to Sida

Our overall recommendation to Sida, in line with the conclusions drawn above, is to assist developing countries in any way possible to preserve and/or restore maximum flexibility in the design and level of national IPR protection.

There are two main avenues for Sida to assist with this. First, and potentially most important, to act on a policy level to influence the Swedish government's position in relevant aspects. Second, to offer direct assistance to developing countries in this context.

At least the following policy options should be taken up for consideration by the international community, and as appropriate be raised by Sida in its dialogue with the Swedish government:

- To repeal TRIPS and return international IPR coordination to WIPO
- To renegotiate TRIPS with a strictly trade-related focus
- To abandon the single undertaking and make TRIPS optional for WTO members
- To allow wider exceptions to patentability, including
 - general exceptions with less restrictions
 - living organisms
 - pharmaceuticals
- To require the following references in patents covering living organisms:
 - sources of the genetic material
 - sources of traditional knowledge used to obtain material
 - evidence of fair and equitable benefit sharing
 - evidence of prior informed consent to patenting from previous holder
- To require inclusion of traditional knowledge as prior art in patent examination
- To expand the scope of geographical indication protection beyond wines and spirits
- To clarify the right to use existing flexibility in the agreement, in line with Article 1

Apart from raising the policy options above in the dialogue with the Swedish government, Sida should support:

- Studies on the implications of repealing the TRIPS agreement;
- Targeted information and awareness raising of government ministries and authorities in their respective fields in respect of international trade agreements and intellectual property rights;
- Actions to increase the coherence of developing country policies, e.g. by workshops and training across ministries and departments, bringing together e.g. ministers of health, agriculture and trade to reach a common understanding of critical issues and of the interrelated nature of economic and social welfare and human rights;
- NGO efforts to raise awareness of the general public and of governments in developing countries.
- Developing country governments' development of IPR legislation and policies and in particular assist in the full use of options available at present in TRIPS to promote a fair balance of interests;

- Development of innovative and workable ways of protecting indigenous and traditional knowledge as part of developing country sui generis legislation, and the exchange of experience between governments regarding problems and achievements in the implementation of such legislation.

Annex 1. Terms of Reference (in Swedish)

Carl-Gustaf Thornström/SAREC
UPPDRAGSBESKRIVNING 2000-07-07

Prospektiv studie av TRIPS i Sveriges internationella utvecklingsamarbete

Målgrupp

Målgrupp för studien är:

- Sidas personal
- Departement och myndigheter

1. Bakgrund

1995 bildades WTO, World Trade Organization som idag omfattas av de flesta av jordens länder. WTO kan sägas utgöra en paraplyorganisation för de olika regelkomplex som tillsammans utgör det multilaterala handelssystemet. WTO-avtalen innebär att många områden som tidigare betraktades som inrikespolitik nu har dragits in under internationella regler. En av grundpelarna i WTO:s regelverk är TRIPS-avtalet. Det är ett regelsystem som innehåller miniminormer för olika immaterialrätter (patent, upphovsrätt och varumärken). Alla länder måste erbjuda patentskydd för produkter och metoder under 20 år. Länder som bryter mot avtalet drabbas av olika straffande handelshinder. TRIPS-avtalet är det avtal inom WTO som väckt mest kritik från u-länder och NGO:s . Det är mycket långtgående och kommer att förändra vår syn på mycket som vi hittills tagit för givet. TRIPS-avtalet ger företag möjligheter att ta patent på liv t ex. gendrag, cellinjer, isolerade proteiner, och transgent utsäde. Detta väcker många nya frågor och möjligheter.

TRIPS-avtalet kommer att påverka småböndernas situation i u-länderna och den biologiska mångfalden. Man är genom avtalet tvungen att skydda växtsorter genom antingen patent eller växtförädlingsskydd (sui generis-skydd). Patenträtter kan främst utnyttjas av stora företag medan det kontinuerliga förädlingsarbete som utförts av generationers bönder inte skyddas. De kunskaper som förvaltas på annat sätt än som privat egendom ges inget skydd av TRIPS-avtalet. Detta kan enligt vissa ståndpunkter begränsa bl.a. böndernas möjligheter att använda hemodlat utsäde. Även den biologiska mångfalden anses av en del vara hotad.

En annan, för u-länderna viktig sektor som påverkas av TRIPS-avtalet är handeln med läkemedel. På sikt kan enligt vissa prognoser u-ländernas tillgång till livsnödvändiga läkemedel till en rimlig kostnad drastiskt minskas.

2. Vilka områden är särskilt relevanta inom utvecklingsamarbetet?

Växtförädling

Ett område där TRIPS-avtalet kommer att få genomgripande konsekvenser, särskilt för u-länderna, är växtgenetik. TRIPS-avtalet ger möjlighet till patentering av genetiska resurser vilket får stor påverkan för växtförädling, utsäde och den biologiska mångfalden. Inom detta område kommer TRIPS-avtalets konsekvenser att vara omvälvande och föra med sig helt förändrade förutsättningar för odling och

växtförädling. I värsta fall kan enligt vissa bedömningar västerländska bolag med hjälp av patentskydd skaffa sig en fullständig kontroll över världens jordbruksproduktion.

Biologisk mångfald

Variationen bland kulturväxterna utarmas i dag snabbt. Bevarandet och utvecklandet av framför allt växtsorter kommer även i framtiden att vara beroende av småbönders arbete och erfarenhet. I biodiversitetskonventionen betonas behovet av artskydd *in situ* dvs att växter och djur bevaras i sin naturliga miljö. Storföretagens ökande inflytande på jordbruket kan enligt vissa bedömningar förväntas medföra ökning av ensidig växtsortföljd och minskad variation av grödor. Med hjälp av patenträtten kan västerländska företag ta över strategiska delar av den genetiska rikedom som idag förvaltas av människor i Syd.

Läkemedel

De flesta av jordens läkemedelsväxter finns i Syd. Förädling och handel med naturläkemedel och läkemedelssubstanser skulle vara en tillgång för många u-länder. Här innebär TRIPS-avtalet både möjligheter och problem beroende på om u-länderna själva kan patentera och förädla sina tillgångar eller om patenteringen tas över av i-ländernas stora företag. Läkemedelssektorn påverkas starkt av TRIPS-avtalet. Avtalet är gynnsamt för i-ländernas läkemedelsindustrier men kan för u-länderna medföra att deras möjlighet att få tillgång till livsnödvändiga läkemedel genom bl.a. parallellimport och egen tillverkning av i-världen patenterade läkemedel kommer att begränsas.

3. Sidas engagemang inom områden i u-länderna som påverkas av TRIPS-avtalet

TRIPS-avtalet berör områden som är ytterst vitala för Sidas samarbetsländer: jordbruk, hälsa och biologisk mångfald. Det är därför naturligt att Sida, bl.a. genom den planerade studien, måste öka sin kunskap och sitt engagemang om konsekvenserna av TRIPS-avtalet för u-länderna. Sida konfronteras nu med stigande intensitet med frågor och propåer rörande biosäkerhet, WTO:s regelverk i relation till CBD, nationell tillträdeslagstiftning rörande genetiska resurser, FAO:s internationella åtagande rörande genetiska resurser för livsmedel, biologisk mångfald och den framtida tillgången på livsnödvändiga läkemedel.

För att öka kunskapen och skapa en plattform för det fortsatta arbetet inom området, skall en studie tas fram. Den skall ge en generell förståelse för TRIPS' regelverk samt ge djupare kunskap om de strategiska områden som särskilt starkt berör Sidas samarbetsländer.

I bilaga 1 redovisas pågående Sida insatser, vilka på olika sätt och i olika grad kopplar till policy- och substansfrågor inom WTO/TRIPS-, CBD- och FAO-processerna.

4. Studiens innehåll

Studien om TRIPS-avtalets konsekvenser för u-länderna skall i sin slutrapport omfatta högst 40 sidor. Fokus skall ligga på identifiering av strategiska frågor illustrerade med konkreta exempel. En delrapport ska avges den 31 augusti 2000, en substansrapport ska avges vid Sidas fattigdomskonferens den 20 till 21 november 2000 och slutrapport ska avges till Sida senast den 30 november 2000.

Studien skall på ett klart sätt beskriva TRIPS-avtalet samt sambanden mellan TRIPS-avtalet och dess möjliga/förväntade konsekvenser för u-länderna inom främst tre områden: Växtförädling, biologisk mångfald och läkemedelstillgång. Studien skall koppla konsekvenserna av TRIPS-avtalet inom dessa områden till de biståndspolitiska målen och fokusera på avtalets betydelse för särskilt fattigdomsbekämpning, miljö och biologisk mångfald, mänskliga rättigheter och ekonomiskt oberoende.

Studien skall vidare ge förslag på hur Sida kan stödja u-länderna att tillgodose sina specifika intressen och positioner vid införlivande av TRIPS-avtalet.

Följande områden är exempel som bör belysas av studien:

Växtförädling, bioteknik

- Studien skall utifrån de biståndspolitiska målen illustrera vad i WTO-, CBD-, och FAO-processerna som är särskilt relevant för och eventuellt problematiskt i det framtida utvecklingssamarbetet bilateralt och multilateralt.
- Exempel på frågor att belysa är TRIPS betydelse för fortsatt tillämpning av gårdsundantaget enligt UPOV-91; ökad utlandskontroll av nationell utsädesproduktion i u-länder, ökad användning av patenterat cum transgent utsäde vs gårdsundantaget/patentintrång.
- FAO:s åtagande och hur ett ev. överenskommet multilateralt system för tillträde/utbyte och kompensation rörande genetiska resurser för livsmedel och jordbruk relaterar till patent/växsortsskydd samt Sui generis skydd.
- Gårds- och forskarundantag för patenterat material i LDC-länder. Segmenterade marknader. Staters suveränitet vs multilaterala företag.
- Företagssammanslagningar inom utsäde, läkemedel- och agrokemi inkl. konsekvenser för tillgänglighet för fattiga grupper till immaterialrättsligt skyddande livsnödvändigheter som idag ligger inom det allmänna och är fritt tillgängligt.
- Kartläggning av människans arvs massa, särskilt etniskt homogena gruppers skydd enligt CBD art 8j rörande förhandsinformerat medgivande och ömsesidiga villkor, etnobiologin, medicinalväxters tillträdesvillkor enl CBD samt TRIPS Sui generis alternativ.

Biologisk mångfald

- Konsekvenserna av TRIPS för lokalsamhällena i LDC-länderna med hänsyn taget till deras nyttjande av medicinalväxter. Eventuella följd effekter för den vilda (icke odlade) biologiska mångfalden.
- Former för skydd av traditionell kunskap och lantraser av odlingsmaterial på nationell nivå enligt CBD art 8J, moderna utsäden och upprätthållande av agrobiodiversitet.

Läkemedelstillgång i u-länderna

- Nuvarande situationen för handel och prissättning rörande läkemedel skall beskrivas.
- TRIPS –avtalets förväntade inverkan på tillgången av livsnödvändiga läkemedel i u-länderna.
- Möjligheterna till ”Compulsory licensing” enligt TRIPS artikel 31 skall belysas
- Klargörande av betydelsen av TRIPS artikel 39, ”Date exclusivity”
- Innebörden av TRIPS artiklarna 7 och 8 (syftar till att balansera rättigheter och skyldigheter för tillverkare och brukare av läkemedel) skall beskrivas och jämföras med den faktiska verkligheten

- Möjliga revideringar och tolkningar av TRIPS-avtalet för att förbättra u-länders tillgång till livsnödvändiga läkemedel

Bilaga 1

Present Sida support to CBD/TRIPS-linked activities

1. CGIAR. The CG-centers and especially the IPR-advisory unit at ISNAR provide information mainly to CG-centers but also to NARS
2. Support to selected DCs involved in WTO Round table/Integrated framework may request support on CB/TRIPS-issues from WIPO and the Swedish PO (planned)
3. ACTS provide advice to DCs in Africa on CBD/TRIPS-policyissues
4. Strengthening (CBD-) taxonomic capacity in DC by training courses etc.
5. Crucible II: Science& policy since 1994 relating to genetic resources (= GR) and IPR plus annotated legislative options for the protection of biological innovation; traditional knowledge and access to GR. Please visit Internet: www.idrc.ca/crucible with codewords crucible and idrc for further information. First book in print April 2000
6. Harmonization of national policies for the management of GR. Analysis of why there is partial breakdown in the FAO-commission on GR. Book being published in May and presented at the GFAR-meeting in Dresden and the CGIAR MTM-meeting in Dresden
7. Bioearn. Regional programme East Africa in biotechnology and biopolicy i e linking "science" to IPR especially transfer and exchange of genetic material and technology in a proprietary context
8. SADC-genebank . A similar progarm is in progress for East Africa
9. Community biodiversity. Test projects on ways and means to in situ conservation and utilization.
10. Support to NGOs like GRAIN, TWN etc for advocacy work
11. FAO-facilitation. Support to informal consultations with key stakeholders in order to facilitate the formal FAO/IUnegotiation process.
12. Awarenessbuilding in OECD-countries thourgh seminars, publications etc on crosscutting policyissues involving FAO/WTO/CBD/UPOV/EU etc.

In total the funding amounts to around 20 million SEK during year 2000

Kommentarer som vidhäftas ToR:

Patric Landin HÄLSO i e-mail till Livsgruppen 2/6-2000.

Beträffande ToR för TRIPS studien så har vi följande synpunkter;

Kap. 2. Vilka områden....., Stycke 3: Läkemedel

Vi tycker inte att "förädling och handel med naturläkemedel och läkemedelssubstanser.." bör vara en central utgångspunkt i studien. Ur ett hälsoperspektiv är tillgång till livsnödvändiga läkemedel till en rimlig kostnad av större relevans (se kap 1, stycke 2 och sista meningen). Vi instämmer med de specifika områdena för studierna angivna under kap. 4, sista stycket; Läkemedelstillgång i U-länderna.

Kap. 4 Studiens innehåll, Växtförädling, bioteknik, pkt 1;

"Studien ska utgå från.....". Vi ser gärna att ni lägger till WHO till listan eftersom de är int. normgivande i läkemedelsfrågan. (Detta gäller antagligen även bilaga 1).

I övrigt tycker vi att ToR är bra. För kännedom så har vi avropsavtal med läkemedelsspecialtister på ICHAR/KI. V.b står vi gärna till tjänst med att förmedla kontakter med dessa. Det går också bra att dra på våra samarbetspartners inom detta område, t ex WHO och Health Action International.

Annex 2. Persons interviewed

Intergovernmental organisations

- OAU

Johnson Ekpere, Director, Scientific, Technical and Research Commission

- South Centre

Rashid Kaukab

Francis Mangeni

- WHO

Nick Drager, Department of Health in Sustainable Development

Debra Lipson, Department of Health in Sustainable Development

German Velasquez, Department of Essential Drugs and Medicines Policy

- WIPO

Shakeel Bhatti, Global Intellectual Property Issues Division

Donna Ghelfi, Global Intellectual Property Issues Division

- WTO

Adrian Otten, Director, Intellectual Property Division

Thu-Lang Tran Wasescha, Counsellor, Intellectual Property Division

Gabrielle Marceau, Legal Affairs Division

Delegations Geneva

- Brazil

Francisco Cannabrava

- Dominican Republic

Federico Cuello

- Guatemala

Rosemarie Luna

- India

Mohan Kumar

- Kenya

Nelson Ndirangu

- Philippines

Leo Palma

Swedish government

- Environment Ministry
Linda Hedlund
Robert Andrén

- Foreign Ministry
Anders Ahnlid

NGOs

- Biothai
Witoon Lianchamroom

- Center for International Environmental Law
Catherine Monagle

- Genetic Resources Action International
Henk Hobbelink
Renée Vellvé

- Lutheran World Federation
Peter Prove

- Médecins sans frontières
Ellen t'Hoën
Christine Gavin

- Quaker United Nations Office
Brewster Grace
Geoff Tansey

- Third World Network
Cecilia Oh

Others

- Environmental Protection Agency, Ethiopia
Tewolde Berhan Gebre Egziabher

- Working Group on Traditional Resource Rights
Graham Dutfield

Annex 3. Websites

*Description of relevant websites*¹⁸

Convention on Biological Diversity: CBD

<http://www.biodiv.org>

Search possibilities are accessible directly via the clickable links on the CBD website itself or via the Clearing-House Mechanism. The search-engine offers the opportunity to search on the CBD site or on biodiversity related websites on the entire Internet.

FAO Commission on Genetic Resources for Food and Agriculture

<http://web.icppgr.fao.org/home.htm>

The CGRFA reviews and advises FAO on policy, programmes and activities related to the conservation, sustainable use and equitable sharing of benefits derived from the utilisation of genetic resources of relevance to food and agriculture. The site gives a quick access to declarations, agreements, codes of conducts, and global mechanisms and instruments. In addition, up-dated information on news, events and meetings is provided.

FAO Plant Genetic Resources for Food and Agriculture (PGRFA)

<http://web.icppgr.fao.org/home.htm>

This site provides access to similar issues as portrayed by the FAO Commission but its information (e.g. on the Global Plan of Action and the State of the World) is more often displayed in HTML-format and, therefore, more quickly accessible.

GRAIN

<http://www.grain.org>

Genetic Resources Action International (GRAIN) is an international non-governmental non-profit organisation, established in 1990, to help further a global movement of popular action against genetic erosion. GRAIN is registered in Spain and has offices in Barcelona and in Los Baños, the Philippines. This site provides access to information on publications and on subscription to e-mail lists on specific topics. The site is fully compatible in English, French and Spanish.

International Plant Genetic Resources Institute: IPGRI

<http://www.cgiar.org/ipgri>

As a CGIAR centre, IPGRI has a mandate to advance the conservation and use of genetic diversity for the well-being of present and future generations. Its site provides access to information on IPGRI itself (e.g. mandate, vision, strategy, impact), issues on genetic resources (e.g. conservation, legal and policy matters), networks, events, training opportunities, country related interventions.

International Union for the Protection of New Varieties of Plants: UPOV

<http://www.upov.org>

On this simple but very easily accessible site one can find all necessary information related to UPOV such as its role and functions, the full text of the convention (Acts of 1961, 1978, 1991), National Plant Variety Protection Laws, membership, ratification situation, addresses, meetings, press releases, documents and publications.

News Bulletins

<http://www.newsbulletin.org/>

¹⁸ This is an adapted version of information compiled by Kees Manintveld, ETC Ecoculture, the Netherlands

This site is managed by the Institute for Agriculture and Trade Policy and provides links to different News Bulletins.

Rural Advancement Foundation International: RAFI

<http://www.rafi.org>

RAFI is an international non-governmental organisation headquartered in Canada. RAFI's focus is the conservation and sustainable improvement of agricultural biodiversity and socially responsible development of technologies useful to rural societies. RAFI organises campaigns and publishes thematic documentation.

Third World Network

<http://www.twinside.org.sg>

The Third World Network is an independent non-profit international network of organizations and individuals involved in issues relating to development, the Third World and North- South issues. TWN conducts research and publishes reports, books and magazines on economic, social and environmental issues pertaining to the South publish books and magazines. The site provides access to frequently updated information and publications on issues related to TRIPS and developing countries.

UK Agricultural Biodiversity Coalition: UKabc

<http://dSPACE.dial.pipex.com/ukfg/ukabc.htm>

Although this site has a focus on biodiversity aspects in the United Kingdom, it is also a gateway to information on international biodiversity and property rights issues. It takes four basic aspects, i.e. sustaining agricultural biodiversity, governance, genetic engineering, and property rights and benefit sharing, as entry points for further searching. A special page offers a large quantity of links to other sites covering international, national, government and non government organisations.

World Intellectual Property Organization: WIPO

<http://www.wipo.org/eng/main.htm>

The site is accessible in English, French and Spanish and provides official information on all internationally agreed treaties related to intellectual property rights. The search possibility gives access to discussions on the relationship between patenting and plant and animal life forms.

World Trade Organisation: WTO

<http://www.wto.org/wto/intellec/intellec.htm>

This site provides information with regard to news, works of the TRIPS council, notifications, reviews of members' implementation of legislation, technical cooperation and disputes. The special page Community/Forums is meant for involving NGOs in TRIPS issues. A page with Frequently Asked Questions gives introduction into some elementary TRIPS aspects. The site is accessible in English, French and Spanish via the home page. One then finds the way to TRIPS via "trade topics".

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