

**STUDY ON THE RELATIONSHIP
BETWEEN THE AGREEMENT ON
TRIPS AND BIODIVERSITY RELATED
ISSUES**

Final Report

Final Report

for

DG TRADE European Commission

Submitted by

**CEAS Consultants (Wye) Ltd
Centre for European Agricultural Studies**

in association with

Geoff Tansey

and

Queen Mary Intellectual Property Research Institute

Telephone: *44 (0)1233 812181

Fax: *44 (0)1233 813309

E-mail: info@promar-ceas.com

CEAS 1843/CIEC

September 2000

Contents

Introduction.....	1
SECTION A	3
1. Description of international activities.....	3
1.1. International organisations and forums.....	3
1.1.1. The World Trade Organisation (WTO)	3
1.1.1.1. Institutional structure and key members	3
1.1.1.2. Relevant activities and decision making procedures	4
1.1.1.3. Overall influence and importance of activities	5
1.1.1.4. Overview of future developments in activities and likely outcomes.....	5
1.1.2. The World Intellectual Property Organisation (WIPO)	7
1.1.2.1. Institutional structure and key members	7
1.1.2.2. Relevant activities	7
1.1.2.3. Overall influence and importance of activities	9
1.1.2.4. Overview of future developments in activities and likely outcomes.....	10
1.1.3. The Convention on Biological Diversity (CBD)	11
1.1.3.1. Institutional structure and key members	11
1.1.3.2. Relevant activities	11
1.1.3.3. Overall influence and importance of activities	13
1.1.3.4. Overview of future developments in activities and likely outcomes.....	14
1.1.4. The United Nations Conference on Trade and Development (UNCTAD)	16
1.1.4.1. Institutional structure and key members	16
1.1.4.2. Relevant activities and decision-making procedures.....	16
1.1.4.3. Overall influence and importance of activities	17
1.1.5. The Food and Agriculture Organisation (FAO) and the IUPGR.....	18
1.1.5.1. Institutional structure and key members	18
1.1.5.2. Relevant activities and decision-making procedures.....	18
1.1.5.3. Overall influence and importance of activities	21
1.1.5.4. Overview of future developments in activities and likely outcomes.....	21
1.1.6. The Consultative Group on International Agricultural Research (CGIAR)	22
1.1.6.1. Institutional structure and key members	22
1.1.6.2. Relevant activities	22
1.1.6.3. Overall influence and importance of activities	23
1.1.6.4. Overview of future developments in activities and likely outcomes.....	24
1.1.7. International Union for the Protection of New Varieties of Plants (UPOV)	24
1.1.7.1. Institutional structure and members.....	24
1.1.7.2. Relevant activities	24
1.1.7.3. Overall influence and importance of activities	25
1.1.7.4. Overview of future developments	25
1.1.8. Organisation for Economic Co-operation and Development (OECD)	25
1.1.8.1. Institutional structure and key members	25
1.1.8.2. Relevant activities and decision-making procedures.....	25
1.1.8.3. Overall influence and importance of activities	26
1.1.9. Commission on Sustainable Development (CSD)	26
1.1.9.1. Institutional structure.....	26
1.1.9.2. Relevant activities	26
1.1.9.3. Overview of future developments in activities	27

1.1.10. South Centre	27
1.1.10.1. Structure and membership	27
1.1.10.2. Activities	27
1.1.10.3. Overall influence and importance of activities	27
1.2. International Business Associations	27
1.2.1. Union of Industrial and Employers' Confederations of Europe (UNICE)	28
1.2.1.1. Structure and membership	28
1.2.1.2. Relevant activities	28
1.2.1.3. Position.....	29
1.2.1.4. Overall influence and importance of activities	29
1.2.2. International Chamber of Commerce (ICC)	30
1.2.2.1. Structure and membership	30
1.2.2.2. Relevant activities	30
1.2.2.3. Position.....	31
1.2.2.4. Overall influence and importance of activities	31
1.2.3. The European Association for Bio-industries (EUROPABIO).....	32
1.2.3.1. Structure and membership	32
1.2.3.2. Relevant activities	32
1.2.3.3. Position.....	33
1.2.3.4. Overall influence and importance of activities	33
1.2.4. International Federation of Pharmaceutical Manufacturers Associations (IFPMA)	33
1.2.4.1. Structure and membership	33
1.2.4.2. Activities	33
1.2.4.3. Position.....	34
1.2.4.4. Influence and importance	34
1.2.5. European Federation of Pharmaceutical Industries and Associations (EFPIA)	35
1.2.5.1. Structure and membership	35
1.2.5.2. Activities	35
1.2.5.3. Position.....	35
1.2.6. International Association for the Protection of Industrial Property (AIPPI)	35
1.2.6.1. Structure and members.....	35
1.2.6.2. Activities	35
1.2.6.3. Position.....	36
1.2.6.4. Influence and importance	36
1.2.6.5. Overview of future developments in activities	36
1.2.7. International Association of Plant Breeders (ASSINSEL)	36
1.2.7.1. Structure	36
1.2.7.2. Activities	37
1.2.7.3. Position.....	37
1.2.7.4. Influence and importance	38
1.2.8. European Chemical Industry Council (CEFIC)	38
1.2.8.1. Structure	38
1.2.8.2. Activities	38
1.2.8.3. Position.....	38
1.2.8.4. Influence	39
1.2.9. Novo Nordisk.....	39
1.2.9.1. Structure	39
1.2.9.2. Activities and position.....	39

1.2.10. General business organisations' position and influence	39
1.2.10.1. Position.....	39
1.2.10.2. Influence	40
1.3. Non-business NGOs.....	40
1.3.1. Genetic Resources Action International (GRAIN).....	41
1.3.1.1. Structure and activities	41
1.3.1.2. Position.....	41
1.3.1.3. Influence	41
1.3.2. Rural Advancement Foundation International (RAFI)	42
1.3.2.1. Structure and activities	42
1.3.2.2. Position.....	42
1.3.2.3. Influence	42
1.3.3. Third World Network (TWN)	43
1.3.3.1. Structure and activities	43
1.3.3.2. Position.....	43
1.3.3.3. Influence	43
1.3.4. Institute for Agriculture and Trade Policy (IATP).....	44
1.3.4.1. Structure and activities	44
1.3.4.2. Position.....	44
1.3.4.3. Influence	44
1.3.5. The Indigenous Peoples' Biodiversity Network (IPBN)	44
1.3.5.1. Structure and activities	44
1.3.5.2. Position.....	45
1.3.5.3. Influence	45
1.3.6. ACTIONAID	45
1.3.6.1. Structure and activities.....	45
1.3.6.2. Position.....	45
1.3.6.3. Influence	46
1.3.7. Centre for International Environmental Law (CIEL)	46
1.3.7.1. Structure and activities	46
1.3.7.2. Position.....	46
1.3.7.3. Influence	47
1.3.8. The GAIA Foundation.....	47
1.3.8.1. Structure and activities	47
1.3.8.2. Position.....	47
1.3.8.3. Influence	48
1.3.9. Greenpeace	48
1.3.9.1. Structure and activities	48
1.3.9.2. Position.....	48
1.3.9.3. Influence	48
1.3.10. International Institute for Sustainable Development (IISD).....	48
1.3.10.1. Structure and activities	48
1.3.10.2. Position.....	49
1.3.11. World Wide Fund for Nature (WWF)	49
1.3.11.1. Structure and activities	49
1.3.11.2. Position.....	49
1.3.11.3. Influence	50
1.3.12. QUNO	50

1.3.12.1. Structure and Activities.....	50
1.3.12.2. Position.....	50
1.3.12.3. Influence	50
1.3.13. General NGOs position and influence	50
1.3.13.1. Position.....	50
1.3.13.2. Influence	51
SECTION B	53
2. Linkages between IPRs and biodiversity-related issues	53
2.1. The legal relationships	53
2.1.1. The multilateral legal context of trade and environment.....	53
2.1.2. CBD and TRIPS – legal conflicts	53
2.1.2.1. Treaty objectives.....	54
2.1.2.2. Treaty interpretation	55
2.1.2.3. Legal interpretation of the interaction between CBD and TRIPS	56
2.1.2.4. Possible legal issues raised by the interaction	61
2.1.3. (Legal) issues raised by the International Undertaking (IU)	71
2.1.3.1. The ‘marketisation’ of biological resources	72
2.1.3.2. Human genetic materials.....	73
2.1.3.3. Ex situ collections outside of the CBD	73
2.1.4. Implications of legal analysis	74
2.2. The practical and policy relationships.....	75
2.2.1. Overview	75
2.2.2. Social and cultural development	76
2.2.2.1. Intrinsic ethical concerns.....	76
2.2.2.2. Consequentialist ethical concerns	78
2.2.3. Economic Issues	78
2.2.3.1. Effects of IPRs	78
2.2.3.2. Market structure and power.....	80
2.2.3.3. R&D.....	81
2.2.4. Environmental Sustainability.....	83
2.2.5. Farming systems	84
2.2.6. Agricultural biodiversity.....	85
2.2.7. Flexibility in implementation.....	87
2.3. Some practical impacts on policy	89
SECTION C	93
3. Provision of technical and financial assistance.....	93
3.1. General requirements	93
3.1.1. Under TRIPs	93
3.1.2. Under the CBD.....	93
3.2. EU Commission technical and financial assistance	96
3.2.1. DG Development.....	96
3.2.2. DG Environment.....	96
3.2.3. DG Research	97
3.3. Member State technical and financial assistance	99
3.3.1. German financial and technical assistance	99
3.3.1.1. German institutions providing assistance and areas of interest.....	99
3.3.1.2. Assistance provided for implementing the CBD	101
3.3.1.3. German assistance for biotechnology.....	108

3.3.2. Technical and financial assistance provided by the UK	110
3.3.2.1. UK institutions providing assistance and areas of interest.....	110
3.3.2.2. Assistance provided for implementing TRIPs.....	110
3.3.2.3. Financial and technical assistance provided to biodiversity	110
3.3.3. Swedish technical and financial assistance	117
3.3.3.1. Swedish institutions providing assistance and areas of interest	117
3.3.3.2. Assistance provided for implementing TRIPs.....	117
3.3.3.3. Assistance provided to biodiversity.....	117
3.3.4. Danish technical and financial assistance	118
3.3.4.1. Assistance provided for implementing TRIPs.....	118
3.3.5. Technical and financial assistance provided by the Netherlands	119
3.3.5.1. Assistance provided for implementing TRIPs.....	119
3.4. Conclusions.....	120
SECTION D	123
4. Assessment	123
4.1. EC objectives	123
4.2. EC internal policy making	123
4.3. Recommendations for action	124
4.3.1. On implementation issues.....	124
4.3.2. On more fundamental questions	125
Appendix 1: List of stakeholders and organisations consulted.....	127
Appendix 2: CBD	129
Appendix 3: A proposal for a global bio-collecting society.....	131

Introduction

The Directorate-General for Trade of the European Commission requested a study on the relationship between the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) and Biodiversity related issues.

The main objective of the study was to provide the Commission with a comprehensive background document on the relationship between IPRs as covered by the provisions of the TRIPs Agreement and biodiversity related issues. The study also required the consultants to develop proposals for enhanced integration of the Commission's objectives, as well as suggestions for priorities to be considered by the Commission.

This final report presents the findings of the project, and provides an assessment of the main elements detailed in the terms of reference (TOR), namely:

- Description of international activities (Section A);
- Definition and in-depth examination of interlinkages between the IPRs and biodiversity issues (Section B);
- Technical and financial assistance, overview and development (Section C);
- Assessment (Section D).

SECTION A

1. Description of international activities

This section of the report identifies, describes and summarises work done in international fora in relation to IPRs and biodiversity related matters, and provides an overview of likely future developments at the international for a level.

The analysis in this section is founded on a combination of desk research, literature review and face to face and telephone discussions with the key stakeholders. The stakeholders involved represent a range of differing perspectives on the issues, and cover organisations and institutions with a regulatory and technical function, developing country and develop country interests, industry representatives and NGOs. A list of the stakeholders spoken to is presented in Appendix 1.

In accordance with our proposal and the study terms of reference, we have established the following for the principal International Institutions and Forums (for example, the WTO, CBD, WIPO, UNCTAD, FAO, CGIAR, UPOV):

- Institutional structures and key members
- Relevant activities and decision making procedures
- Overall influence and importance of activities
- Future developments in activities and likely outcomes.

In addition to this, we have detailed the structure, activities, position and influence for the key International Business Associations involved with IPRs (for example, UNICE, ICC, IFPMA, Europabio, AIPPI, ASSINSEL), and the principal non-business NGOs active in the area of TRIPs and biodiversity (for example, GRAIN, RAFI, TWN, IPBN, WWF, ACTIONAID, GAIA).

1.1. International organisations and forums

1.1.1. The World Trade Organisation (WTO)

1.1.1.1. Institutional structure and key members

The WTO administers the most comprehensive multilateral trade agreements. The WTO operates on the principle that a liberalised system of international trade based on non-discrimination and the elimination of trade barriers is essential to global well-being. Primarily, the WTO functions are the following:

- administers the WTO Trade Agreements (including TRIPS);
- provides the common institutional framework for the conduct of trade relations amongst its members;
- acts as a forum for multilateral trade negotiations;
- administers the trade dispute settlement;
- monitors national trade policies;
- provides technical assistance and training for developing countries;
- co-operates with other international organisations.

There are currently some 135 members of the WTO. In the TRIPS/IPR field, the key developed (and more pro-IPR) Members are the United States, Canada, the European Union and Japan. In the developing world, the key actors among the more anti-IPR Members are India¹, Egypt and Malaysia and some of the Latin American countries.

1.1.1.2. Relevant activities and decision making procedures

Two WTO bodies are of particular relevance to this study. These are the Council for TRIPS, which oversees the functions of the TRIPS Agreement, and the Committee on Trade and Environment (CTE). In sharp contrast with meetings of the Conference of the Parties to the CBD, neither are open to the public. This is a source of criticism of the institution by many non-governmental organisations (NGOs). However, many WTO members much prefer to negotiate behind closed doors. Essentially decisions are made by consensus.

1. The Council for TRIPS

The Council for TRIPS is responsible for:

- monitoring the operation of TRIPS, and in particular members' compliance;
- affording members the opportunity to consult on matters relating to trade-related IPRs;
- assisting members in the contest of dispute settlement procedures; and
- carrying out other duties assigned to it by the members (Article 68).

It appears that to date, few if any discussions held by the Council have analysed the relationships between TRIPS and the environment. In marked contrast, this issue is a key item on the work programme of the Committee on Trade and Environment. However, the review of Article 27.3(b) has led a range of countries to raise a number of environment-related issues. The whole TRIPS Agreement is scheduled to be reviewed by the Council during 2000 in accordance with its built-in agenda.

2. The Committee on Trade and Environment (CTE)

The CTE is not a rule making body, but a WTO discussion fora. CTE has encouraged observer status from other institutions and the FAO and IPGRI often attend. The 1994 Marrakesh Ministerial Decision on Trade and Environment, which set out the CTE's terms of reference, required the CTE, which was formally established by the General Council the following year, to consider the relevant provisions of TRIPS "as an integral part of its work". To this effect, Item 8 of the CTE's work programme is *The Relevant Provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights*.

In November 1996, the Committee adopted its Report to the Singapore Ministerial Conference². The Report concluded that further work was needed to appreciate better the relationship of the relevant provisions of TRIPS to environmental protection and sustainable development and whether and how these provisions relate to:

"the creation of incentives for the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising from the utilisation of genetic resources including the protection of knowledge, innovations and

¹ See for example, WT/GCM/147.

² World Trade Organisation - Committee on Trade and Environment (1996) *Report of the WTO committee on Trade and Environment*. WTO, Geneva. (Press/TE 014)

practices of indigenous and local communities embodying traditional lifestyles relevant to the conservation and sustainable use of biodiversity”.

The CTE Secretariat prepared a paper at the end of February 2000 about the CBD and TRIPS, but this was merely a case study overview, with no substantive analysis (eg, comparing different approaches), and with no solutions and proposals. Traditional and indigenous knowledge has been discussed during several CTE meetings, and a few governments have argued in favour of the need to reform the patent system and to protect indigenous knowledge, such as through trade secrets and *sui generis* systems consistent with CBD Article 8 (j).

The critical views sometimes aired at CTE meetings, especially by countries such as India, Egypt and Malaysia, imply that WTO members have yet to achieve a consensus and that some have for the time being agreed to disagree. The CTE deliberations evince a strong disagreement among members about the relationship of multilateral environmental agreements (MEAs) like the CBD to WTO rules. It seems that India has been the most consistently critical of TRIPS in terms of its relationship with the CBD.

1.1.1.3. Overall influence and importance of activities

Most of the world trading system is now governed by a series of agreements, known as the WTO Agreement and its Annexes, that define the rights and the obligations of WTO Members and direct their policies toward economic liberalisation. The WTO has therefore become one of the most important international organisations, providing the institutional setting for negotiating and enforcing global rules for international trade and economic activity. As the volume of international trade increases, both in absolute terms and as a percentage of total production, the role of the WTO is likely to continue to grow.

The WTO is also the world's most powerful intergovernmental trade regulator on IPR, due to the TRIPS Agreement. Though TRIPS does not aim at identical national IP laws -- nor does it establish a world patent system as such - it nevertheless requires every WTO Member to introduce its own patent system if it does not have one already and set minimum standards for Members to follow. The WTO's dispute settlement procedure creates a strong mechanism for compliance, including the power to impose trade sanctions against Members that fail to abide by its binding decisions.

1.1.1.4. Overview of future developments in activities and likely outcomes

According to the built-in agenda of TRIPS, the Council must review the implementation of the whole Agreement in 2000, and at two-year intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of TRIPS.

Some developing countries have worked together to put forward common proposals and positions. For example, Bolivia, Colombia, Ecuador, Nicaragua, and Peru put forward a proposal on protection of traditional knowledge³, and the African Group submitted an important proposal on TRIPS also to the General Council prior to the Seattle Ministerial Conference⁴. A number of developing countries are proposing to re-open the negotiations and amend the language of Article 27.3 (b). They are advocating an expansion of what may be excluded from patentability under TRIPS to provide member states with the option of fully excluding all biological materials from patentability. Some of these

³ See WT/GCW/362.

⁴ See WT/GCW/302.

countries also appear interested in the possibility of devising *sui generis* systems for plant varieties that are only partially modelled on the UPOV Convention.

Table 1.1: Official developing country proposals for the review or re-negotiation of TRIPS (1999)⁵

Stakeholder	Patenting (life forms & biological processes)	<i>Sui generis</i> (plant varieties)
Kenya ⁶	- Need five-year extension of transition period - Harmonise TRIPS with CBD	- Need five-year extension of transition period - Increase scope of 27.3(b) to include protection of indigenous knowledge and farmers' rights - Harmonise TRIPS with CBD
Venezuela ⁷	In 2000, introduce mandatory system of IPR protection for traditional knowledge of indigenous and local communities, based on the need to recognise collective rights	
Africa Group ⁸	- Review should be extended + additional five year transition after that - Review should clarify that plants, animals, microorganisms, their parts and natural processes cannot be patented	- Review should be extended + additional five year transition after that - <i>Sui generis</i> laws should allow for protection of community rights, continuation of farmers' practices and prevention of anti-competitive practices which threaten food sovereignty - Harmonise TRIPS with CBD and FAO
LDC Group ⁹	- There should be a formal clarification that naturally occurring plants and animals, as well as their parts (gene sequences), plus essentially biological processes, are not patentable. - Incorporate provision that patents must not be granted without prior informed consent of country of origin - Patents inconsistent with CBD Art 15 (access) should not be granted - Need for extended transition period	- <i>Sui generis</i> provisions must be flexible enough to suit each country's seed supply system - Need for extended transition period
Jamaica, Sri Lanka, Tanzania, Uganda, Zambia ¹⁰ , SAARC ¹¹	No patenting plants without prior informed consent of government and communities in country of origin	
SADC ¹²	There is a need to prevent piracy of traditional knowledge built around bio-diversity and to seek the harmonisation of the TRIPS Agreements with the UN Convention on Biological Diversity so as to ensure appropriate returns to traditional communities. - The transitional period for implementation of 27.3(b) should be extended and the 2000 review should be delayed. - The review of 27.3(b) should harmonise TRIPS with CBD. - The exclusion of essentially biological processes from patentability should extend to microbiological processes.	- The transitional period for implementation of 27.3(b) should be extended and the 2000 review should be delayed. - The review of 27.3(b) should retain the <i>sui generis</i> option.

⁵ Table taken from GRAIN, "For a Full Review of TRIPS 27.3(b) – An update on where developing countries stand with the push to patent life at WTO", March 2000

⁶ WT/GC/W/23 of 5 July 1999

⁷ WT/GC/W/282 of 6 August 1999

⁸ WT/GC/W/302 of 6 August 1999

⁹ WT/GC/W/251 of 13 July 1999

¹⁰ <http://www.foe.org/international/wto/govt.html> of 2 September 1999

¹¹ WT/L/326 of 22 October 1999

¹² WT/L/317 of 1 October 1999.

Stakeholder	Patenting (life forms & biological processes)	<i>Sui generis</i> (plant varieties)
G77 ¹³ Bolivia, Colombia, Ecuador, Nicaragua, and Perú ¹⁴	Future negotiations must make operational the provisions relating to the transfer of technology, to the mutual advantage of producers and users of technological knowledge and seek mechanisms for a balanced protection of biological resources and disciplines to protect traditional knowledge The Seattle Ministerial Conference should adopt a mandate to: (a) carry out studies in order to make recommendations on the most appropriate means of recognising and protecting traditional knowledge (TK) as the subject matter of IPR; (b) initiate negotiations with a view to establishing a multilateral legal framework that will grant effective protection to the expressions and manifestations of TK; (c) complete the legal framework envisaged in paragraph (b) above in time for it to be included as part of the results of the new round of trade negotiations.	

Hence, it is possible that the 2000 TRIPS review could *inter alia* lead to a wider acceptance of alternative plant variety systems devised specifically with the CBD's objectives in mind, and even to the removal of the requirement to patent life-forms. However, developed countries are generally opposed to this and ultimately consensus will be required for any amendments to Article 27.3 (b). Given the contentious nature of plant and animal patenting, the most likely outcome in the near future is that the present text will remain unaltered since developing countries are now forming blocs which issue common positions generally hostile to the raising of IPR minimum standards, at least without some balancing new provisions for protecting traditional knowledge.

1.1.2. The World Intellectual Property Organisation (WIPO)

1.1.2.1. Institutional structure and key members

WIPO is one of the 16 specialised agencies of the United Nations and is responsible for the promotion and protection of intellectual property internationally through co-operation among States. WIPO is also responsible for the administration of the various multilateral treaties dealing with the legal and administrative aspects of intellectual property. It is under WIPO's auspices that countries agree to negotiate new IPR treaties and revise existing ones (except for TRIPS and the UPOV Convention). WIPO has 171 member states.

WIPO's primary objectives are to:

- *administer* 19 international treaties on intellectual property laws (such as the Paris Convention on the Protection of Intellectual Property and the Berne Convention on the Protection of Literary and Artistic Works);
- *provide* assistance to member states in promulgating intellectual property laws;
- seek *harmonisation of national laws*, aiming to promote the protection of intellectual property throughout the world.

1.1.2.2. Relevant activities

1. The Global Intellectual Property Issues Division

In 1997, WIPO established its Global Intellectual Property Issues Division (GIPID), to deal with:

“The challenges facing the intellectual property system in a rapidly changing world, such as accelerating technological advancement, the integration of the world's economic,

¹³ WT/MIN(99)/3 of 2 November 1999

¹⁴ WT/GC/W/362 of 12 October 1999

cultural and information systems, and the expanding relevance of intellectual property issues in trade, culture, investment, human rights, health and environmental spheres”.

GIPID focuses on four specific areas¹⁵: Protection of Traditional Knowledge, Innovation and Creativity; Biotechnology and biodiversity; Protection of Folklore; and Intellectual Property and Development. The various issues researched and explored under these activities include:

- (a) *New approaches to the use of IPRs for new beneficiaries* concerning:
 - (i) the intellectual property needs of holders of traditional knowledge, innovations, culture and genetic resources, such as in agriculture and medicine;
 - (ii) the feasibility of establishing databases of traditional knowledge; and
 - (iii) the international legal character of IPRs arising from references to intellectual property in multilateral instruments in other fields, such as human rights, the environment, culture, trade, health and investment.
- (b) *Biodiversity and biotechnology* with a focus on:
 - (i) the role of IPRs in the preservation, conservation and dissemination of global biodiversity;
 - (ii) the IPR aspects of biotechnology; and
 - (iii) the use of IPRs in the transfer of technology under multilateral environmental agreements.
- (c) *Protection of expressions of folklore* including:
 - (i) the need for, and possible nature and scope of, new or adapted forms of protection for expressions of folklore; and
 - (ii) the use of the existing intellectual property system for the beneficial commercialisation of expressions of folklore, such as by way of multimedia and Internet technologies.

2. Other relevant WIPO activities

WIPO set up a Working Group on Biotechnology consisting of representatives of *governments* and *the private sector* “to identify issues related to biotechnology and intellectual property rights, which may be included in the WIPO work program beginning in the 2000-2001 biennium, as determined by its Member States”¹⁶. It met in November 1999 and the participants agreed to produce a document containing recommendations on areas relating to five themes including:

- Legal standards related to the scope and character of patent protection for inventions in the field of biotechnology;
- The relationship between patents and other forms of intellectual property protection for biotechnological inventions (e.g., UPOV-style plant variety protection, trade secrets and geographical indications); and
- The nature of the relationship between patent systems and certain issues, including the moral or ethical dimensions of commercialisation of inventions involving genetic alteration of plants or animals, *the conservation and preservation of the environment (including the protection of biological diversity)* and the protection of animal and human health (including such issues as biosafety, food security and sustainable development).

¹⁵ See Draft Programme and Budget 2000-2001, WIPO, 1999.

¹⁶ <http://www.wipo.int/biotech/index-eng.html>

The group has now produced its list of issues that might be studied by WIPO and has fulfilled its mandate. It is now up to WIPO's Member States to decide which of these issues are taken up in the Organisation's future work on IPRs and biotechnology.

- In addition to being an arena for governments to exchange views on IPR issues, WIPO has set up Commissions made up of individuals from outside the organisation to guide its work.
- In 1998, WIPO established an Industry Advisory Commission (IAC) to advise the Director-General on IPR matters of specific interest to industry. According to a November 1999 press release¹⁷, at its inaugural meeting, the Director-General said:

"the establishment of the IAC marked "an historic shift in the policy of this Organisation and in the vision which we would like to have for this universal body" ... [and will] "ensure that, in particular, our norm-setting activities and the global protection systems will meet with the interests and needs of your respective institutions, industry and the market sector interests".

- In 1999 WIPO set up another commission, the Policy Advisory Commission (PAC)¹⁸. This is "a purely advisory body composed of high-level and experienced policy-makers from the world of politics, diplomacy, law and public administration". In a press release, the Director-General called on Commission members of the Commission to:

"offer their views on .. issues .. relating to how WIPO, as guardian of global intellectual property legislation and harmonised practices, can keep pace with rapid technological changes so that developments like the Internet will not dislocate or undermine the international intellectual property superstructure".

The PAC's membership includes IPR professionals favouring strong global regulatory standards and eminent individuals from developing countries (with little or no experience of IPRs)¹⁹.

1.1.2.3. Overall influence and importance of activities

Although WIPO remains an important body for international standard setting on IPR and developing legislation, it is overshadowed by the WTO TRIPS Agreement. Amongst other factors, unlike the WTO, WIPO does not have a dispute settlement mechanism.

This difference provides strategic opportunities well known to a number of governments. On the one hand, this is one of the main reasons why the developed countries worked hard to ensure that one of the outcomes of the Uruguay Round was an IPR agreement promoting minimum standards throughout the world while allowing members to challenge perceived failures of other members to implement these standards. On the other, some may derive advantages from offloading certain topics onto WIPO, discussion of which in a trade-related setting does not serve the interests of the most powerful WTO members. Traditional knowledge seems to be one such issue.

¹⁷ PR/99/196.

¹⁸ See WIPO Press Releases No. 164 of 13 April 1999, No. 165 of 15 April 1999 and No. 166 of 15 April 1999.

¹⁹ Among the former are: Martin Bangemann, Member of the European Commission for Industrial Affairs and Information and Telecommunications Technologies; Hisamitsu Arai, Vice-Minister for International Affairs, Ministry of International Trade and Industry, Japan; and Bruce Lehman, President, International Intellectual Property Institute, former US Assistant Secretary for Commerce and Commissioner of Patents and Trademarks, and also former lobbyist for the Business Software Alliance. In the

This does not mean that WIPO is becoming marginal to the global IPR regime. Indeed, WIPO is by far the most important international institution *dedicated* to IPRs, and is likely to increase its influence as WIPO continues to build closer links with other institutions such as the WTO and the CBD Conference of the Parties and Secretariat. Moreover, WIPO is collaborating with WTO to help developing countries to meet their TRIPS obligations through provision of technical assistance, for example, “in preparing legislation, training, institution-building, and modernising intellectual property systems and enforcement”²⁰.

1.1.2.4. Overview of future developments in activities and likely outcomes

The proposed GIPID program for 2000/2001 includes:

- *Protection of traditional knowledge, innovations and creativity*: the work program includes the commissioning of a study on customary law and regulatory systems that apply to the protection of informal knowledge, the commissioning of a feasibility study on the use of IP law or practice to protect informal knowledge and the organisation of an annual Round-Table on the protection of traditional knowledge for the holders of such knowledge²¹.
- *Biotechnology and biodiversity*: the program will include an examination of the social, economic and ethical implications of IPRs in relation to the Human Genome Project and the commissioning of a study on the IP aspects of access to and benefit-sharing in biological resources.
- *Protection of folklore*: the program includes the convening of several expert meetings to examine alternatives for the development of standards for the protection of folklore.
- *Intellectual property and development*: the program includes a seminar on the role of IP in economic, social, cultural and technological development and the preparation and dissemination of a study on the role of IP in the transfer of environmentally sustainable technology to developing countries with reference to obligations under multi-lateral arrangements.

It is difficult at this stage to predict where the GIPID's activities will lead. So far the bulk of its activities have been concerned with fact-finding. The outcome could be an updated version of the 1985 UNESCO/WIPO *Model Provisions for National Laws on Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions*, though – it must be said – this has attracted little interest from national legislatures, or even a treaty.

It is highly likely that there will be no substantive result. The main reason is that certain industrialised countries may be using WIPO to keep traditional knowledge out of the WTO leaving it as a marginal issue. It would appear, though, that several developing countries are now cognisant of this possibility and are seeking to insert negotiations on traditional knowledge into the next WTO trade round. Bolivia, Colombia, Ecuador, Nicaragua, and Peru jointly recommended to the WTO General Council that there be established “a multilateral legal framework that will grant effective protection to the expressions and manifestations of traditional knowledge”²².

latter group are Prince El-Hassan Bin Talal of Jordan; Fidel Ramos, former President of the Philippines; and the late Julius Nyerere, former President of Tanzania.

²⁰ Joint WTO-WIPO press release, 21 July 1998.

²¹ The Round-Table has already been held in 1998 and 1999.

²² WT/GC/W/362.

1.1.3. The Convention on Biological Diversity (CBD)

1.1.3.1. Institutional structure and key members

The CBD is a legally binding international *framework* for the conservation and sustainable use of all biological diversity. The three main objectives of the CBD are (a) the conservation of biological diversity; (b) the sustainable use of its components; and (c) the fair and equitable sharing of its benefits arising from such use.

The CBD:

- re-affirms national sovereignty over genetic resources and stresses the importance of *in situ* conservation.
- is generally interpreted to emphasise a bilateral approach to access/exchange negotiations between sovereign source countries and recipients.
- recognises the central role of indigenous and local communities in biodiversity conservation through their traditional and sustainable practices and knowledge systems.
- acknowledges intellectual property rights with the understanding that such rights should promote and not compromise the Convention's objectives.
- is expected to not only oversee and monitor but also to stimulate financial and other resources that will support the conservation and sustainable use of biodiversity.

Resolution three of the Nairobi Final Act, recognised that *Ex situ* Collections of genetic resources formed before the entry into force of the CBD, and Farmers' Rights as outstanding issues, that should be resolved through negotiations at FAO (see below).

There are currently 175 CBD member states (notably, the US has yet to ratify the Convention). Active members include several Latin American countries, as well as India, Malaysia Indonesia, Kenya and Ethiopia. Various European countries are known for their active involvement in the CBD's review and policy-making forums. The Spanish government hosted the two main meetings on Article 8 (j) held so far (see below) while the Scandinavian governments are associated with positions that are supportive of the interests of developing country parties. The main institutional structures are the Secretariat based in Montreal and the Conference of the Parties (COP).

1.1.3.2. Relevant activities

1. The Secretariat

The Secretariat's functions, as set out in Article 24 of the Convention, are to:

- arrange for and service meetings of the Conference of the Parties;
- perform the functions assigned to it by any protocol;
- prepare reports on the execution of its functions under this Convention and present them to the Conference of the Parties;
- co-ordinate with other relevant international bodies and, in particular to enter into such administrative and contractual arrangements as may be required for the effective discharge of its functions; and
- perform such other functions as may be determined by the Conference of the Parties.

2. CBD Conference of the Parties (COP)

The mandate of the COP is to review the implementation of this Convention (Article 23) by *inter alia*:

- considering and adopting, as required, protocols, and amendments to this Convention and its annexes;
- contacting, through the Secretariat, the executive bodies of conventions dealing with matters covered by this Convention with a view to establishing appropriate forms of co-operation with them; and
- considering and undertaking any additional action that may be required for the achievement of the purposes of this Convention in the light of experience gained in its operation.

To review implementation of the CBD, the Conference of the Parties meets at 1-2 year intervals. At its 3rd meeting (COP-3) in November 1996, two of the agenda items were *Implementation of Article 8 (j)*, and *Intellectual Property Rights*. At COP-4 in May 1998, there was no agenda item dealing exclusively with IPRs, but the subject came up in a number of decisions, including the Decision IV/8 on *Access and Benefit Sharing*.

Decision II/15 of the Conference of the Parties in 1995 recognised the special nature of agricultural biodiversity, that its distinctive features and problems needed distinctive solutions, and declared its support for dealing with these through the development of the Global Plan of Action for Plant Genetic Resources, through the Leipzig International Technical Conference under the auspices of FAO, and for the revision of the Undertaking on Plant Genetic Resources (IU) at FAO. At COP-3 in Decision III/11, the Parties expressed a willingness, should the FAO Conference so wish, for the revised IU to take the form of a protocol to the Convention.

a) Article 8 (j)

With respect to Article 8 (j), COP-3 agreed on the need to “develop national legislation and corresponding strategies for the implementation of Article 8 (j) in consultation with representatives of their indigenous and local communities” [Decision III/14]. Pursuant to this, the CBD Secretariat arranged a Workshop on Traditional Knowledge and Biodiversity. The Workshop took place in Madrid, Spain in November 1997, and was attended by representatives of governments and 148 indigenous and local community organisations. The Report of the Workshop suggested the following options for recommendations for elements of a work plan for future elaboration under the framework of the CBD²³:

- (a) participatory mechanisms for indigenous and local communities;
- (b) status and trends in relation to Article 8 (j) and related provisions;
- (c) traditional cultural practices for conservation and sustainable use;
- (d) equitable sharing of benefits;
- (e) exchange and dissemination of information;
- (f) monitoring elements; and
- (g) legal elements.

At COP-4 in May 1998, Decision IV/9 on *Implementation of Article 8 (j) and Related Provisions* recognised “the importance of making intellectual property-related provisions of Article 8 (j) and related provisions of the Convention on Biological Diversity and provisions of international agreements relating to intellectual property mutually supportive, and the desirability of undertaking further co-operation and consultation with the WIPO”.

²³ Convention on Biological Diversity Secretariat (1997) *Report of the Workshop on Traditional Knowledge and Biological Diversity*. Madrid, 24-28 November 1997. UNEP/CBD/TKBD/1/3.

b) Intellectual property rights

The COP-3 decision on *Intellectual Property Rights* (Decision III/17) called, *inter alia*, for dissemination of case studies on the relationships between IPRs and CBD objectives, including technology transfer and benefit-sharing with indigenous and local communities. It was suggested that these case studies consider matters such as (i) the role and potential of *existing* IPR systems in enabling 'interested parties', including indigenous and local communities to determine access and equitable benefit sharing, and (ii) the development of IPRs, such as *sui generis* systems. Though COP-4 did not deal with IPRs as an agenda item, Paragraph 10 of Decision IV/15²⁴ expressed agreement on the need for further work to enhance understanding of the relationship between IPRs, TRIPS and the CBD²⁵.

IPRs have been discussed at various meetings of the COP and its subsidiary body, though no decision has been reached about the impacts of IPRs on the objectives of the Convention. With respect to access to genetic resources and benefit sharing, some Parties believe that existing IPRs could be instrumental in benefit sharing mechanisms because they could allow users of genetic resources to generate revenues from their inventions, which they could share with countries of origin or local communities. Others believe that existing IPRs do not serve this purpose, they are inadequate to protect the rights of farmers and indigenous peoples, and that these laws constitute one of the greatest threats to the future conservation and enhancement of biodiversity. IPRs, they assert, do not promote benefit sharing.

Intellectual property remains a topic of interest to the COP given that the relationship between IPRs, TRIPS and the CBD was a major part of the agenda of the June 1999 Intersessional Meeting on the Operations of the Convention. Accordingly, the COP has come to pay special attention to discussions in other fora concerning IPRs. The Secretariat has asked for and been granted observer status to the Committee on Trade and Environment of WTO and is seeking observer status to the TRIPS Council.

1.1.3.3. Overall influence and importance of activities

The overall scope of the CBD is significant, requiring protection of all biodiversity in all types of ecosystems and habitats. It is not self-enacting, requiring each member country to put its own law in place. Furthermore, unlike the WTO, it has no enforcement mechanism and has no dispute settlement procedure.

This has meant that the implementation of the CBD has proceeded slowly, further affected by a lack of finances and the difficulty of prioritising such an expansive subject area among 175 Parties with diverse national situations and interests. There is also a level of political uncertainty created by the failure of the US Government to ratify the Convention. Nevertheless, governments have worked reasonably well in establishing important negotiating fora for indigenous knowledge and the analysis of scientific and technical issues.

²⁴ "The relationship of the Convention on Biological Diversity with the Commission on Sustainable Development and biodiversity-related conventions, other international agreements, institutions and processes of relevance".

²⁵ The COP "emphasises that further work is required to help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Convention on Biological Diversity, in particular on issues relating to technology transfer and conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources, including the protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity."

As with the TRIPS Agreement however, the CBD is internationally legally binding. Some countries argue that the CBD has preference over the WTO while others insist that this is a political absurdity and that they are both complementary. The possibility of the TRIPS Agreement impeding the implementation of the objectives of the CBD has incited lively discussion in the WTO and CBD, as well as amongst many organisations in civil society and industry. The link between the two Agreements relates *inter alia* to the importance of protecting various forms of knowledge that may be utilised for fulfilling the objectives of the CBD. Specifically, there is a need to protect and more widely apply scientific and technical knowledge about biological and genetic material including the biodiversity-related knowledge, innovations and practices of indigenous and local communities. The system of allocating rights in knowledge that is established under the TRIPS Agreement suggests a role for IPRs in the implementation of the CBD. The possible legal and practical policy conflicts between the TRIPS Agreement on the implementation of the CBD are discussed in Section 2 of this report.

The recently concluded agreement on a Biosafety Protocol is interesting since it is clearly a trade-related treaty which was negotiated and concluded outside of the WTO. Since it is such a recent and specific legal agreement, according to the principles of international law, it should take precedence where there is conflict between its provisions and the WTO rules. Even where no specific conflicts arise, principles of international law indicate that the Protocol can be used as a legally authoritative source of clarifying language in cases where particular WTO rules are subject to conflicting interpretations. The specific relationship between the Biosafety Protocol and the WTO rules may well be tested in the near future through the latter's dispute settlement mechanism.

1.1.3.4. Overview of future developments in activities and likely outcomes

Two important meetings this year are the *Ad hoc* Working Group on Article 8(j) (Seville, 27 - 31 March), and the Fifth Meeting of the COP (Nairobi, 15 - 26 May).

Ad hoc Working Group on Article 8(j)

The Parties agreed to establish an *ad hoc* open-ended inter-sessional working group to address the implementation of Article 8 (j) and related provisions to be composed of Parties and observers including, in particular, representatives of indigenous peoples and local communities. The mandate of the working group, which had its first meeting in Seville in March 2000, included the following items:

- to provide advice on the application and development of legal and other appropriate forms of protection for the knowledge, innovations and practices of indigenous and local communities.
- to develop a programme of work, based on the structure of the elements in the Madrid report (see above).

As part of the work programme's short-term activities, governments, international agencies, research institutions, representatives of indigenous peoples and local communities and NGOs were invited to submit case studies and other relevant information to the Executive Secretary as background information for the working group on such topics as:

- The influence of international instruments, IPRs, current laws and policies on knowledge, innovations and practices of indigenous and local communities.
- Documented examples and related information on ethical guidance for the conduct of research in indigenous and local communities about the knowledge they hold.
- Matters of prior informed consent, fair and equitable sharing of benefits and *in situ* conservation in lands and territories used by indigenous and local communities.

Three items on the *Ad hoc* Working Group agenda²⁶ had IPR-related subject matters:

- application and development of legal and other appropriate forms of protection for the knowledge, innovations and practices of indigenous and local communities.
- implementation of Article 8(j) and related provisions, in particular the development and implementation of a programme of work at national and international levels.
- development of a programme of work on Article 8(j) and related provisions of the CBD.

Discussions under the first of these agenda items resulted in a final recommendation which included *inter alia*:

- a call for case studies to enable an assessment of the effectiveness of legal instruments and other forms of protection;
- the recognition of *sui generis* systems and transmission of COP findings to the WTO and WIPO;
- a reaffirmation of the importance of making Article 8(j) and other international IPR agreements mutually supportive;
- an invitation to review or develop national legislation, including *sui generis*, interim or other systems to protect traditional knowledge;
- a request for support to develop national registers of traditional knowledge; and
- reference to ensuring the participation of indigenous and local communities in the negotiation of conditions for access and use of their knowledge.

Cooperation with WIPO

According to the COP-4 decision to establish the Working Group (IV/9), the Executive Secretary of the CBD was requested to seek ways to enhance co-operation with WIPO and encourage Parties to submit information to the Executive Secretary to support such co-operation. The potential for the COP working with WIPO to influence the international IPR regime in favour of the CBD's objectives and the rights of indigenous peoples and local communities is an intriguing one. All three of the following outcomes are conceivable albeit unlikely:

- (a) a new IPR treaty to protect traditional biodiversity-related knowledge, innovations and practices;
- (b) a more general agreement to protect traditional culture and folklore as was suggested in the Plan of Action from the 1997 *UNESCO-WIPO World Forum on the Protection of Folklore* which might include biodiversity-related knowledge; or
- (c) a Protocol to the CBD to implement protection of traditional biodiversity-related knowledge and/or Farmers' Rights.

COP-5

At COP-5, access to genetic resources will be one of the priority issues for review and guidance²⁷. There is no doubt that IPRs will be debated, since many governments take the view that the two issues are closely related.

²⁶ UNEP/CBD/WG8J/1/1.

²⁷ UNEP/CBD/COP/5/1.

1.1.4. The United Nations Conference on Trade and Development (UNCTAD)

1.1.4.1. Institutional structure and key members

UNCTAD is a permanent intergovernmental body, and the principal organ of the United Nations General Assembly in trade and development. It has 188 member states. Many intergovernmental and non-governmental organisations have observer status and participate in its work.

UNCTAD is also the focal point within the UN for the integrated treatment of development and interrelated issues in the areas of trade, finance, technology, investment and sustainable development²⁸.

1.1.4.2. Relevant activities and decision-making procedures

UNCTAD pursues its goals through research and policy analysis, intergovernmental deliberations, technical co-operation, and interaction with civil society and the business sector. UNCTAD meets every four years at Ministerial level to formulate policy guidelines and set work priorities.

In preparation for the tenth Conference (UNCTAD X), the group of 77 developing countries (G77) and China met and issued a declaration, "The Marrakech Declaration"²⁹, which "reaffirm[s] the role of UNCTAD as the principal forum of the United Nations for the integrated treatment of development and interrelated issues in the areas of trade, money and finance, investment, technology, commodities, competition and sustainable development."

UNCTAD supports capacity-building by organising training programmes for developing country representatives participating in multilateral negotiations, and by providing technical co-operation on sustainable commercialisation of biodiversity ("The Biotrade Initiative").

The Biotrade Initiative

The UNCTAD Biotrade Initiative was launched in 1996, in collaboration with the Secretariat of the CBD. It claims to be "a new approach to biodiversity conservation and sustainable development". For developing countries to benefit from increased private sector interest in bioprospecting, conducive conditions for an efficient and equitable bioprospecting market need to be established by overcoming the following obstacles:

- (i) property rights to biological resources that are not well defined or easily protected;
- (ii) insufficient information about these resources to determine their actual and potential value;
- (iii) high transaction costs and undeveloped risk spreading mechanisms; and
- (iv) lack of technical and entrepreneurial resources. The Initiative advocates effective economic instruments and strategic partnerships as a means to bring value to biological resources, achieve appropriate technology transfers, and enhance export capacity for developing countries in such resources.

The Biotrade Initiative makes no assertions that existing IPR regimes are incompatible with conservation, sustainability or equitable benefit sharing. Indeed, the UNCTAD Secretariat paper on

²⁸ <http://www.unctad.org/en/aboutorg/aboutorg.htm>

²⁹ UNCTAD (1999) TD/381.

the Biotrade Initiative³⁰ argues that the availability of IPR protection provides incentives for more generous technology transfer and technical assistance arrangements. The paper also proposes that the Conference of the Parties to the CBD consider an international certification system for bioprospecting linked to a code of conduct. Resulting products from bioprospecting and R&D that comply with the code's requirements could then carry this certification. Patent laws could even be amended to require such certification for applications on inventions developed from biological resources. Moreover, in a section dealing with enhancing conservation and sustainable development opportunities, the paper argues that:

"on equity grounds it is ... essential that information provided by traditional healers, farmers or other local residents which is used to identify potentially valuable biological materials, is obtained through informed consent and results in appropriate compensation".

The paper goes on to mention that mechanisms have been proposed or are being used to promote equitable sharing, local development and incentives for biodiversity conservation, and these mechanisms will be evaluated by the Initiative. Among such mechanisms to be evaluated are:

- communal intellectual property rights over information concerning uses for components of biodiversity; and
- certification of origin programmes for local suppliers of biological material.

So far the bulk of the Initiative's work has focused mainly on South America.

1.1.4.3. Overall influence and importance of activities

In the 1970s UNCTAD produced a series of critical studies on IPRs. UNCTAD had the competence to deal with negotiations on the trade-related aspects of IPRs but any regulatory outcomes were unlikely to have been optimal for developed countries. Even so, UNCTAD continues to be interested in IPRs and can bring to bear a high level of technical expertise in its work in the IPR field. For example, in 1996 the organisation published a useful booklet on TRIPS and developing countries³¹.

As both an institution and a forum on trade, the developing countries continue to consider UNCTAD to be of utmost importance, in spite of the way certain developed countries have sought to marginalise it. Developing countries have over the years benefited from the one-member one-vote rule of decision-making which is much more favourable to them than weighted voting based on financial contributions or consensus. In addition, bloc-voting was allowed so the G77 was able to exert a powerful influence on UNCTAD. Overview of future developments in activities

With respect to future multilateral trade negotiations, the G77 and China urged at their UNCTAD X preparatory meeting that particular attention be given *inter alia* to "seek[ing] mechanisms for a balanced protection of biological resources and disciplines to protect traditional knowledge". In the event, the decision was made to include the Biotrade initiative in UNCTAD's plan of action for the coming years, enabling it to develop the programme in full as a technical co-operation activity worldwide. UNCTAD is forming the basic team to conduct and supervise its development and the speed of expansion will depend on donor support. The Spanish Government has offered to provide some facilities to support the Biotrade initiative in Seville.

³⁰ UNCTAD (1996) *The Biotrade Initiative: A New Approach to Biodiversity Conservation and Sustainable Development*. Study prepared by the UNCTAD Secretariat for the Conference of the Parties to the Convention on Biological Diversity.

³¹ UNCTAD (1996) *The TRIPS Agreement and Developing Countries*. United Nations, New York and Geneva.

UNCTAD expects to work more with WIPO in the future. The aim is to have country programmes working with WIPO, FAO, WHO, whoever is interested, with pilot projects on policy and capacity building.

1.1.5. The Food and Agriculture Organisation (FAO) and the IUPGR

1.1.5.1. Institutional structure and key members

The FAO is the largest autonomous agency within the United Nations system with 180 member states plus the EU. Since its inception, FAO has worked to alleviate poverty and hunger by promoting agricultural development, improved nutrition and the pursuit of food security - the access of all people at all times to the food they need for an active and healthy life. The Organisation offers direct development assistance, collects, analyses and disseminates information, provides policy and planning advice to governments and acts as an international forum for debate on food and agriculture issues³².

In the context of the CGRFA and the IUPGR (see below), 160 countries are Members of the CGRFA and 113 have adhered to the IUPGR. The European Union and its member states individually and other European countries (especially Switzerland and Norway) have been highly active. Other countries that have taken up the IUPGR as an important issue include Australia, Canada, Malaysia, India, Philippines, Japan, Iran, Ethiopia (which is with Malaysia a the leader for developing countries), Angola, South Africa, Tanzania, Morocco, Mexico, Brazil, Peru, Argentina, Uruguay, and Colombia. The United States, traditionally hostile to the IUPGR, has become more constructively engaged recently.

1.1.5.2. Relevant activities and decision-making procedures

Since 1983 the FAO has been developing its Global System for the Conservation and Utilisation of Plant Genetic Resources for Food and Agriculture. The aims of the Global System are the conservation of biological diversity, sustainable use of its components and the fair and equitable sharing of the benefits arising from the utilisation of genetic resources.

There are four main components of the Global System:

- An intergovernmental forum, the *Commission on Genetic Resources for Food and Agriculture* (CGRFA).
- A currently non legally-binding agreement, the *International Undertaking on Plant Genetic Resources* (IUPGR).
- An interim financial mechanism, the *International Fund for Plant Genetic Resources* (IFPGR).
- The Global Plan of Action for the Conservation and Sustainable Utilisation of Plant Genetic resources for Food and Agriculture that was adopted by 150 countries at the 1996 International Technical Conference on Plant Genetic Resources.

The CGRFA

The CGRFA monitors the Global System. It has responsibility for the main institutional component of the Global System, the IUPGR. It also provides an inter-governmental forum where countries can

³² <http://www.fao.org/UNFAO/WHATITIS.HTM>

meet, discuss and reach consensus on an equal footing. It is the negotiating forum where the IUPGR is being revised, in harmony with the CBD.

In 1995 the CGRFA extended its mandate beyond plant genetic resources to encompass all components of biological diversity of interest to food and agriculture, beginning with livestock. It will also encompass biological diversity related to forests and fisheries as these areas relate to food and agriculture. Aside from responsibility for the IUPGR, the Commission also oversees the FAO-CGIAR Trust Agreement and provides policy oversight for the germplasm collections included in that agreement.

The IUPGR

The IUPGR is a currently non-legally binding intergovernmental (multilateral) instrument originally adopted in 1983. 113 countries are signatories. It is intended to facilitate access, conservation and sustainable utilisation of plant genetic resources for food and agriculture. The IUPGR aims to:

- ensure that the need for conservation is globally recognised and that sufficient funds for this purpose are made available;
- assist farmers and farming communities in all regions of the world in the protection and conservation of plant genetic resources and of the natural biosphere;
- allow farmers, their communities and countries to participate fully in the benefits derived, at present and in the future, from the improved use of plant genetic resources through plant breeding and other methods³³.

The international community is currently renegotiating the IUPGR in harmony with the CBD (the 1992 Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity). The CBD, adopted as binding agreement in 1992, covered *all* genetic resources. However, countries also adopted the parallel Resolution 3 of the Nairobi Final Act, which recognised that access to *ex situ* collections not acquired in accordance with the Convention (such as the CGIAR collections) and Farmers' Rights, were outstanding matters which the Convention had not addressed, for which solutions should be sought within FAO. The 1993 FAO Conference accordingly adopted Resolution 7/93, which provided for negotiations among governments for:

- the adaptation of the International Undertaking on Plant Genetic Resources, in harmony with the CBD;³⁴
- consideration of the issue of access on mutually agreed terms to plant genetic resources, including *ex situ* collections not addressed by the CBD;³⁵ and the issue of the realisation of Farmers' Rights.

Negotiations have focussed on the scope of the IU, realising farmers' rights, access on mutually agreed terms to plant genetic resources, including *in situ* and *ex situ* collections, and benefit sharing, all issues with potentially significant implications for the CBD and for IPR. These issues have meant

³³ WT/CTE/125, *op.cit.*, para.11.

³⁴ While the Convention on Biological Diversity covers all types of biological diversity, the scope of the Undertaking is limited to plant genetic resources for food and agriculture.

³⁵ This formula, adopted after careful negotiations, although limited to plant genetic resources for food and agriculture, is not limited only to *ex situ* collections not addressed by the Convention.

that protracted discussions have continued at several extraordinary sessions of the CGRFA with slow progress.

Farmers' Rights, as the term suggests, was originally conceived as a counterpart to Breeders' Rights and is more a political concept than a legal term. Farmers' Rights are a way of recognising that plant genetic resources are different from natural mineral resources like coal and oil, since to assume that plant genetic resources are mere gifts of nature fails to give credit to the knowledge and resource management practices of traditional communities past and present that have nurtured many of these resources. Resolution 5/89 defined Farmers' Rights as:

"Rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources particularly those in the centres of origin/diversity. Those rights are vested in the international community, as trustees for present and future generations of farmers, and supporting the continuation of their contributions as well as the attainment of overall purposes of the IUPGR".

Following much discussion over many negotiating sessions the members of CGRFA agreed an article dealing with them at their Eighth session in 1999 as follows:

Article 15 – Farmers' Rights

15.1 The Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.

15.2 The Parties agree that the responsibility for realizing Farmers' Rights, as they relate to Plant Genetic Resources for Food and Agriculture, rests with national governments. In accordance with their needs and priorities, each Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:

- (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
- (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture;
- (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

15.3 Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate.

Resource questions are no longer linked to Farmers' Rights but to the IU. This compromise was negotiated by the EU, US and India. Mechanisms to give practical expression to Farmers' Rights and to compensate farmers still do not exist and will need to be developed at the national level. Negotiations are continuing over the issues of access and benefit-sharing. The negotiations foresee the creation of a specific Multilateral System of Access and Benefit- Sharing for Plant Genetic Resources for Food and Agriculture, in contra-distinction to the bilateral arrangements that characterise, for example, bio-prospecting for pharmaceuticals under the CBD.

1.1.5.3. Overall influence and importance of activities

The FAO is an important think tank and influencer of developing countries. The FAO has a wide mandate on issues related to all genetic resources for food and agriculture access to these resources and *in* and *ex situ* collections. The FAO also operates a multilateral system, the IUPGR, with a large signatory base, though without a legal basis at present. The COP to the CBD have recognised the need to develop this as the mechanism to govern access and benefit sharing for genetic resources for food and agriculture through revision of the IU.

Until recently, many developed countries have been generally lukewarm about implementing the IUPGR and Farmers' Rights. The ambivalence of developed countries towards the IUPGR may be starting to change. As developing countries increasingly introduce legislation to implement the access and benefit sharing provisions of the CBD, the inherent multilateralism of the IUPGR is seen as a more attractive alternative, more suited to the needs of wide sectors of agriculture (for example to developed countries' seed industries), which appear to be concerned about the effects of the CBD on access. It is increasingly being perceived by the wide range of stakeholders that IU may offer the best opportunity to maintain the exchange of genetic resources that underpin the development of food and agriculture while clarifying access, implementing Farmers Rights and minimising transaction costs involved in tracking the many elements of genetic improvement in a crop which the bilateral approach embodied in the CBD implies. This is a way of reconciling the importance of not unduly restricting cross-boundary flows of genetic resources for food and agriculture with the bilateral approach being promoted by the CBD - which is more appropriate for pharmaceutical bioprospecting.

1.1.5.4. Overview of future developments in activities and likely outcomes

The FAO's new strategic framework looks in a consistent manner at world policy and regulatory frameworks for food and agriculture, in order to establish a coherent analysis enabling an understanding of the interaction, *inter alia* between food and agriculture, related industry and IPRs. FAO will also aim to play a greater role in assistance related to TRIPS and the CBD, in response to the increase in requests for assistance with development of legislation and *sui generis* systems.

The Policy Assistance Division of the Technical Cooperation Department, in response to requests from FAO members, has developed a capacity-building programme for Multilateral Trade Negotiations on Agriculture. They have already run five sub-regional workshops, which include sessions on TRIPS, and plan nine more. The workshops deal with different WTO agreements that affect agriculture, including TRIPS, and will cover about 160 countries, with 5-6 people from each participating in a five day course. The participants are drawn from Agriculture/Trade policy, SPS/Plant & Animal health, and IPRs/PGR.

In the IU, the positions of negotiators turn on the question of access and benefit-sharing, expressed in terms of agreed and predictable resources for agreed projects and programmes, with priority given to the activities of the Leipzig Global Plan of Action in developing countries. Developing countries are generally wary that free access to germplasm will result in a flow of genetic materials to the plant breeding industry, to be adapted and made subject to IPRs with inadequate sharing of benefits. Developed countries advocate free access to genetic resources, with respect of relevant property regimes, including intellectual property. Despite this, the recent less ambivalent position by Northern countries, including the US, means that it is possible that a revised IUPGR could be presented to the FAO Council in November 2000, and adopted as a legally binding agreement at the FAO Conference in November 2001. The main uncertainties as to its final form are:

- whether or not a revised IU should be adopted within the framework of the FAO; and
- whether then FAO Conference will decide that the IU should also be presented to the COP of the CBD for its consideration as a possible protocol (with the understanding that it will be governed by its own Conference of the Parties).

1.1.6. The Consultative Group on International Agricultural Research (CGIAR)

1.1.6.1. Institutional structure and key members

The CGIAR, founded in 1971, is an informal association of public and private donors that supports an international network of 16 international agricultural research centres (IARCs), each with its own governing body. The major sponsors are the FAO, the World Bank, the United Nations Development Programme, the United Nations Environment Programme, Japan, USA and the EU. With a budget of some US\$340 million per annum, the CGIAR oversees the largest agricultural research effort in the developing world.

1.1.6.2. Relevant activities

The mission of the CGIAR is to use research, in partnership with other organisations, to contribute to promoting sustainable agriculture for food security in the developing countries.

The CGIAR network holds the world's largest *ex situ* collections of plant genetic resources for food and agriculture with 600,000 accessions, mainly of traditional varieties and wild crop relatives. These collections are held under the auspices of the FAO "in trust for the benefit of the international community, in particular the developing countries", include up to 40% of all unique samples of major food crops held by gene banks worldwide. This agreement provides an international cover for the collections of the CG Centres, which are not inter-governmental bodies, with the implication that their collections would otherwise be governed by the national laws of their host countries, or owned by these countries. The FAO Commission on Genetic Resources for Food and Agriculture determines the policy under which the network of ex-situ collections operate.

Programmes at the IARCs fall into six broad categories³⁶:

- Productivity Research: creating or adopting new technologies (such as the 'dwarf' varieties of wheat and rice that brought about Asia's and Latin America's Green Revolution) to increase productivity on farmers' fields.
- Management of Natural Resources: protecting and preserving the productivity of natural resources on which agriculture depends.
- Improving the Policy Environment: assisting developing countries to formulate and carry out effective food, agriculture, and research policy.
- Institution Building: strengthening national agricultural research systems in developing countries.
- Germplasm Conservation: conserving germplasm and making it available to all regions and countries.
- Building Linkages: facilitating co-operation and technology transfer between advanced research institutions in developed countries and national research programmes in developing countries.

The International Plant Genetic Resources Institute (IPGRI)

³⁶ <http://www.cgiar.org>

The IPGRI is the focal institution within the CGIAR for biodiversity in general and genetic resources in particular. Unlike the other IARCs, IPGRI does not have research facilities but acts as a catalyst and facilitator. It plays both a leadership/co-ordination function in genetic resources policies and a representational role in appropriate international forums. IPGRI also provides secretariat services to the CGIAR Genetic Resources Policy Committee. The Institute is very concerned about the impact on developing countries and in particular small/subsistence farmers of IPRs in the overall process of developing new technology, in terms of the access that these farmers will have to new technology and methods if they have all been patented.

IPGRI carries out its overall policy role in a number of inter-related activities such as specific activities on policy issues (e.g., studies on alternative IPR regimes and access and ownership of indigenous knowledge) within the context of the IPGRI Plant Genetic Resources Programme. Such activities also involve close collaboration with partner institutions.

IPGRI has been conducting capacity building work to help developing countries design appropriate IPR policy and has published several reports on the issues involved. In October 1999, it published a decision check list for countries developing the *sui generis* system referred to in TRIPS Article 27.3 (b)³⁷.

The CGIAR and IPRs

A rapidly changing IPR environment and increasing privatisation of agricultural research has forced the CGIAR to develop policies and procedures on IPRs over the past decade. The process has been complicated by the fact that the CGIAR system has no legal status, and its members often represent opposing sides of the highly politicised IPR debate. In addition, there are at least 14 'policy-making' bodies within the CGIAR. After years of discussion and debate by numerous committees, the CGIAR system is still in the process of developing a coherent, comprehensive policy on IP. Given the rapidly changing international policy environment and ongoing debate in many international fora, the CGIAR decided to endorse in 1996 "Guiding Principles for the CGIAR Centres on Intellectual Property and Genetic Resources" as an "interim working document that will be continually reviewed and revised".

In 1998 the CGIAR expanded its position on IPRs. The CGIAR called for a moratorium on the granting of IPRs on all plant germplasm held in trust under the FAO's auspices. It confirmed a set of guidelines on genetic resources and IP, which includes the trust agreement on genetic resources with FAO. It also established a special unit at ISNAR to provide legal counsel on IPRs to IARCS.

1.1.6.3. Overall influence and importance of activities

The CGIAR has influence due to the in excess of 40 governments, foundations and research institutions which support it through informal meetings and collegial understandings.

More importantly, the importance of the CGIAR network's work and the size of the ex-situ collections it holds, which are placed in trust for the world community and which it deploys for the benefit of developing countries, means that its policies towards IPR are of great significance. The IARCs routinely distribute elite germplasm free of charge to plant breeders through Material Transfer Agreements (MTAs) which expressly disallow recipients to apply for IPRs on the materials transferred. However, due to several cases of misappropriation, in 1999 the CGIAR Consultative Council asked

³⁷ IPGRI (1999) Key Questions for Decision-makers. Protection of Plant Varieties under the WTO Agreement on Trade-related Aspects of Intellectual Property Rights. Decision Tools. IPGRI, Rome.

the Centre Board Chair's Committee and the Centre Director's Committee to look into the possible next steps. The CGIAR and the IARCs are still considering the development of a co-ordinated IPR policy. It is conceivable that certain IARCs could opt to take out IPR protection of their elite germplasm in order to prevent it from being misappropriated by others and thereby taken out of the public domain. It was reported in early April that the board of one of the Centres, CIMMYT, had approved an IPR policy that will allow patenting as a means of preventing private companies from claiming intellectual-property rights over any of its discoveries or resources.

1.1.6.4. Overview of future developments in activities and likely outcomes

In light of the importance of the CGIAR centres and the ex-situ collection, there is concern among governments and NGOs that aspects of ownership, trusteeship, governance and the rules regarding access to and exchange of CG germplasm be strengthened and clarified.

- Hence, the role of the CGIAR will be debated intensely over the next few years. For example, at the national level, some governments and scientists appear to see international centres as research funding competitors. Some, too, look upon IARCs as undertaking initiatives which may not be compatible with national interests or policies. These views, on occasion, have led to calls to “nationalise” or, at least “regionalise” centres.

1.1.7. International Union for the Protection of New Varieties of Plants (UPOV)

1.1.7.1. Institutional structure and members

The Union has two permanent organs: the Council and the Office of the Union (UPOV). The former consists of the representatives of the member States, and potentially of member inter-governmental organisations. Each member of the Union that is a State has one vote in the Council. The Office of UPOV is under the direction of the Secretary-General, who is, by agreement with WIPO, the same person as the Director-General of WIPO.

Historically, UPOV membership consisted primarily of industrialised nations. In recent years, that has begun to change. With the recent accession of the People's Republic of China, Kenya, Bolivia, Brazil and Slovenia, the total number of UPOV members is 44. The vast majority of UPOV members are either party to the 1978 or the 1991 Act (see below).

1.1.7.2. Relevant activities

UPOV establishes international rules (Acts) under which countries grant intellectual property rights to the developers of new plant varieties (individuals or institutions), known as Plant Breeders Rights (PBRs). The UPOV Act is a “*sui generis* system” as called for under TRIPS 27.3 (b) for countries opting to continue excluding plant varieties from patentability.

The original UPOV Act was revised in 1972, 1978 and 1991. The 1991 UPOV Act does not mandate an exemption allowing farmers to freely use farm-saved seed as further planting material. It does, however, leave each State free to include the farmer's exemption (or farmer's privilege) in national legislation.

In April 1998, the 1991 Act of the Union for the Protection of New Varieties of Plants (UPOV) Convention entered into force. This was supposed to close the door on the twenty year-old 1978 accord, making it impossible to adhere to the 1978 Act from that date onwards. More recently

however, in 1999, India was permitted to become a member of the 1978 UPOV by way of a special waiver. It is not clear whether or not other countries will seek to become members of the 1978 Act, or if they would be allowed to do so, though it seems as if many developing countries would like to have the option of choosing between the 1978 and 1991 Acts.

1.1.7.3. Overall influence and importance of activities

UPOV's influence is derived from the fact that it is an established *sui generis* system for the protection of plant varieties, and with a membership that covers the developed countries and a number of important developing countries. The common perception is that it is gaining prominence as a legislative model for plant breeders' rights because Article 27.3(b) of TRIPS obligates WTO members to adopt patents and/or "an effective *sui generis* system" for plant varieties. Although "effective *sui generis* system" is not defined, UPOV asserts that it is the only internationally recognised *sui generis* system for the protection of plant varieties.

1.1.7.4. Overview of future developments

It is not possible to say whether UPOV will be able to make its Act *the sui generis* alternative to patents for plant varieties. While there is ample scope for national discretion in interpreting the *sui generis* option, a number of influential bodies, such as WIPO, and some countries, are pushing for a narrowing of the *sui generis* option to the legislative model provided by UPOV. However, in some industrialised countries, in particular the US, breeders are moving away from protecting new varieties with PBRs, and are increasingly resorting to patents instead, which is pointing to a shift away from protection under the UPOV act.

1.1.8. Organisation for Economic Co-operation and Development (OECD)

1.1.8.1. Institutional structure and key members

The OECD has 29 member states³⁸, providing a setting in which to discuss, develop and perfect economic and social policy. The work of the OECD Secretariat is financed by the Member countries.

1.1.8.2. Relevant activities and decision-making procedures

Exchanges between OECD governments flow from information and analysis provided by a Secretariat in Paris. Parts of the OECD Secretariat collect data, monitor trends, analyse and forecast economic developments, while others research social changes or evolving patterns in trade, environment, agriculture, technology, taxation and more. This work, in areas that mirror the policy-making structures in ministries of governments, is done in close consultation with policy-makers who will use the analysis, and it underpins discussion by member countries when they meet in specialised committees of the OECD. Much of the research and analysis is published.

Specialised committees meet to advance ideas and review progress in more tightly defined areas of policy - such as trade, public management, development assistance or financial markets. There are about 200 committees, working groups and expert groups. Some 40 000 senior officials from national administrations, come to OECD committee meetings each year to request, review and contribute to work that is undertaken by the OECD Secretariat.

³⁸ This section is mostly summarised from the OECD website (<http://www.oecd.org>).

The OECD has done work on IPRs, particularly in connection with competition policy and biotechnology regulation. For example, OECD produced a synthesis report on intellectual property practices in the field of biotechnology, seen by the organisation as being relevant to discussion on Article 27.3 (b)³⁹. This was co-prepared by Joseph Straus, who is referred to elsewhere in this document as an important actor.

1.1.8.3. Overall influence and importance of activities

While the OECD does not possess direct regulatory powers, it is a highly influential body whose recommendations often inspire policy actions by member states governments. Deliberations at the Committee level may lead to agreements to act in a formal way. For example, the Multilateral Agreement on Investment (MAI) was negotiated within the framework of the OECD from 1995-1998. The MAI aimed to reduce obstacles and inefficiencies to overseas investments and make it easier for corporations to move their investments, both capital and production facilities, across international borders. However, after France withdrew from the MAI, the OECD suspended the negotiations in 1998.

The OECD also has a well organised approach to donors co-ordination, including on biodiversity and sustainable development. Discussions and ideas make for better informed work within their own governments on the spectrum of public policy and clarify the impact of national policies on the international community.

1.1.9. Commission on Sustainable Development (CSD)

1.1.9.1. Institutional structure

The CSD was established in 1993 by the UN Economic and Social Council as one of its functional commissions. The CSD is an inter-governmental entity consisting of 53 UN member states elected to serve three-year terms. The CSD meets annually, and NGOs can attend the sessions as observers. The Secretariat is located within the UN Department for Policy Co-ordination and Sustainable Development (DPCSD) in New York. The CSD works closely with other UN agencies.

1.1.9.2. Relevant activities

The role of the CSD is:

- to review progress at the international, regional and national levels in the implementation of recommendations and commitments contained in the final documents of UNCED;
- to elaborate policy guidance and options for future activities to follow up UNCED and achieve sustainable development;
- to promote dialogue and build partnerships for sustainable development with governments, the international community and the major groups identified in Agenda 21 as key actors outside the central government who have a major role to play in the transition towards sustainable development including women, youth, indigenous peoples, non-governmental organisations, local authorities, workers and trade unions, business and industry, the scientific community, and farmers.

³⁹ OECD (1996) Intellectual Property, Technology Transfer and Genetic Resources. An earlier OECD contribution to biotechnology-related IPRs was the 1985 publication, Biotechnology and Patent Protection: An International Review.

1.1.9.3. Overview of future developments in activities

CSD-8 will take place in New York in April. Trade and Agriculture are two of the four agenda items. UNCTAD is the Task Manager for Trade and Environment and FAO is the Task Manager for Agriculture.

1.1.10. South Centre

1.1.10.1. Structure and membership

The South Centre is an inter-governmental organisation based in Geneva⁴⁰, which has 46 developing country members. *Inter alia* it aims to⁴¹:

- Promote South solidarity, South consciousness and mutual knowledge and understanding among the countries and peoples of the South;
- Promote various types of South-South co-operation and action, South-South links, networking and information exchange;
- Contribute to South-wide collaboration in promoting common interests and co-ordinated participation by developing countries in international forums dealing with South-South and North-South matters, as well as with other global concerns.

1.1.10.2. Activities

The South Centre brings together missions and specialists in workshops with wider participation and smaller groups on specific issues and provides informal papers. It has, in cooperation with others, organised a major seminar for developing country missions on TRIPS in November 1998 and plans follow-up activity during 2000.

1.1.10.3. Overall influence and importance of activities

Despite its small staff, it is regarded as a significant element in strengthening developing countries missions in Geneva through its briefings and workshops.

1.2. International Business Associations

There are four types of pro-IPR organisations that seek to influence IPR law and policy at the international and national levels:

- (1) the multi-sectoral business associations, like the International Chamber of Commerce (ICC) and the Union of Industrial and Employers' Federations of Europe (UNICE). IPRs are one of several issues on which they work;
- (2) the sectoral or multi-sectoral business associations, such as the International Intellectual Property Alliance⁴², which are dedicated specifically to IPRs;
- (3) the sectoral business associations, such as the Pharmaceutical and Research Manufacturers Association, the European Federation of Pharmaceutical Industries and Associations (EFPIA)⁴³,

⁴⁰ Chemin du Champ-d'Anier 17, 1209 Geneva. Tel: +41 22 791 8050; fax: +41 22 798 85 31.

⁴¹ <http://www.southcentre.org>

⁴² The IIPA is based in the United States and consists of copyright industry business associations.

⁴³ Avenue Louise 250 Box 91, B-1050 Brussels, Belgium. Tel: +32 2 626 2555; Fax: +32 2 626 2566

and the International Association of Plant Breeders⁴⁴ (ASSINSEL), which are concerned with several issues including IPRs;

- (4) those expert associations that do not consist of IPR-holding firms, but which support IPRs by such means as training, capacity-building and propagandising. These include the International Association for the Protection of Industrial Property (AIPPI), the International Federation of Intellectual Property Attorneys (FICPI) and the Max Planck Institute for Foreign and International Patent, Copyright and Competition Law.

Some of these corporations and business associations have commented publicly on the relationship between TRIPS and the CBD and/or have made statements or have formulated policies eg, Novo Nordisk and the ICC. Detailed below are the activities, position and influence of a number of these organisations.

1.2.1. Union of Industrial and Employers' Confederations of Europe (UNICE)

1.2.1.1. Structure and membership

UNICE⁴⁵ represents at the European Union more than 16 million companies through its membership of 39 central industrial and employers' federations from 31 European countries. It is made up of the Council of Presidents, the Executive Committee and five Policy Committees (Economic and Financial Affairs; External Relations; Social Affairs; Industrial Affairs; and Company Affairs), which organise UNICE's practical work, and prepare UNICE's position papers on specific policy areas, through 60 Working Groups. The Policy committees create and organise the working groups. In each domain a working group is established whenever there are developments which need debate, and to that group experts are nominated by the member-federations, normally coming from companies in that country.

1.2.1.2. Relevant activities

UNICE is the representative of European business and industry to the European Union and its institutions. It participates on behalf of its members in the various tripartite Committees (such as ECOSOC), the Standing Committee for Employment and in the Social Dialogue. UNICE also performs a similar representative function with EFTA and the OECD.

Its priority mission is "to improve the competitiveness of all companies in Europe and to ensure that their interests are heard, understood and taken into account." To achieve this it:

- promotes the common professional interests of the firms represented by its members;
- informs the decision-making process at European level so that policies and legislative proposals which affect business in Europe take account of companies' needs;
- represents its members in the dialogue between social partners enshrined in the Treaty on European Union.

Included amongst its policy priority areas of interest are European competitiveness, liberalisation of world trade by strengthening the multilateral trading system (based on fair and clear rules), sustainable development through reconciling environmental protection while stimulating the dynamism of European industry, and innovation through targeted policies for research and protection of intellectual property.

⁴⁴ In French: Association Internationale des Selectionneurs pour la Protection des Obtentions Végétales.

⁴⁵ Rue Joseph II, 40/4 - B-1000 Brussels; tel: +32 2 237 65 11; fax: +32 2 231 14 45; email: main@unice.be

As UNICE also represents the European pharmaceutical industry, amongst others, it has close ties with EFPIA, CEFIC and EUROPABIO on issues related to biotechnology and IPRs. In fact these organisations feed into numerous UNICE Working Groups and Policy Committees, with industry IP representatives of UNICE also performing a similar function in other organisations (such as EFPIA).

1.2.1.3. Position

The UNICE position on TRIPS and biodiversity are provided in three papers: (i) TRIPS and the environment, (ii) TRIPS in the context of the Millennium Round, and (iii) the Green Paper on the Community patent and patent system in Europe. In January 2000, UNICE put together a compendium of position papers on a number of specific instruments and debates on intellectual property (including the three mentioned). In these papers, UNICE stated that:

- it is concerned that failure by a substantial number of developing countries to implement TRIPS in a proper and timely fashion will seriously call into question its viability and its value;
- the time is not yet ripe to include intellectual property as a subject for further negotiation in an imminent WTO new global round. The priority for strengthening intellectual property protection at international level is to ensure effective and timely implementation of the TRIPS agreement and pursue the work programme embodied in the built-in agenda;
- the Rio Convention on Biological Diversity and the TRIPS Agreement are two different bodies of law which exist in parallel but do not govern the same subject matter. The obligations under the CBD are not in contradiction with the obligations under TRIPS. The Biodiversity Convention states that it cannot be applied in a manner inconsistent with adequate and effective protection of intellectual property rights (eg, TRIPS) unless the exercise of those rights would cause a serious damage or threat to biological diversity. Article 27.2 of TRIPS allows Members to exclude from patentability inventions the exploitation of which would seriously prejudice the environment;
- it regards article 27.1 of TRIPS as fundamental. It clearly prohibits discrimination as to the place of invention, the field of technology and whether products are imported or locally produced;
- supports the transfer of technology between States providing the terms of this transfer do not amount to a confiscation of private rights;
- it is dismayed that a number of non-governmental organisations seem to oppose effective protection of intellectual property rights on environmental grounds and request amendments to TRIPS (eg, to exclude biotechnological inventions), despite that it is generally recognised that the protection of these rights fosters the invention of products and processes supporting sustainable development and contributes directly to the invention and dissemination of environment-friendly products and processes.

1.2.1.4. Overall influence and importance of activities

UNICE is credited with playing a major role in ensuring that TRIPS was included as one of the Uruguay Round Agreements. Through its representation, Committees, and papers, UNICE can present its positions and interests directly to a number of key institutions with which it has most contact, principally the EU Commission and Parliament. For example, the 2000 compendium position paper was launched at both the Community and international level, and was also presented to high-level persons in both the Commission and the EU Parliament. UNICE hopes that this publication can help European decision-makers to accept and support users' needs in order to build a competitive framework for intellectual property.

International institutions in which UNICE operate on issues of patents and IP are World Health Organisation and to a lesser extent WIPO. UNICE does not get involved with the FAO or have much to do with UNCTAD.

1.2.2. International Chamber of Commerce (ICC)

1.2.2.1. Structure and membership

The International Chamber of Commerce (ICC) is the world business organisation and represents thousands of member companies and associations from over 130 countries.

The ICC is comprised of the following:

- The ICC World Council.
- ICC commissions. Over 500 business experts formulate ICC policy and elaborate its rules in various commissions. Commissions scrutinise proposed international and national government initiatives affecting their subject areas and prepare business positions for submission to international organisations and governments. These policy statements are submitted to national governments and international organisations through ICC national committees and the International Secretariat.
- National committees. These co-ordinate with their membership to address the concerns of the business community and to convey to their governments the business views formulated by ICC.

1.2.2.2. Relevant activities

The ICC's stated purpose is "to promote international trade, investment and the market economy system." The ICC membership establishes the business stance on broad issues of trade and investment policy as well as on vital technical and sectoral subjects. These include financial services, information technologies, telecommunications, marketing ethics, the environment, transportation, competition law and intellectual property, among others. Highlights of ICC activities include:

- The World Trade Organisation. At its regular meetings with ambassadors to the World Trade Organisation, ICC promotes business ideas and objectives for achieving a successful new round of trade negotiations.
- The United Nations. ICC is engaged in intensive dialogue with the United Nations and its Secretary General on how business expertise can help the UN to attain its economic objectives.
- The Group of Seven industrial countries. Every year, the head of the host government of the G7 industrial countries confers with the ICC presidency on the eve of the summit.
- Guides to investment. In a joint project with UNCTAD, ICC enlisted support from 30 major companies in providing guidance to least developed countries on policies and practical steps to attract more foreign direct investment.

The ICC has a Commission on Intellectual and Industrial Property⁴⁶, presently chaired by Dr Ashok Ganguly, Chairman of ICI-India, which normally meets twice a year. This Commission's priorities and interests are *inter alia*:

⁴⁶ For more information contact: Daphne Yong-d'Hervé, Policy Manager, ICC, 38, Cours Albert 1er 75008 Paris; tel: +33 1 49 53 28 27; fax: +33 1 49 53 28 59; email: dye@iccwbo.org. Also, Ashok Ganguly (ashok_ganguly@ici.com).

- to identify emerging intellectual property issues that will have an impact on business;
- examine the intellectual property implications of environmental protection and economic development;
- to raise the profile of intellectual property rights as a business issue;
- implementation of the Uruguay Round agreement TRIPS;
- environment-related intellectual property issues such as the Biodiversity Convention and the protection of biotechnological inventions, in co-operation with the Commission on Environment;
- enforcement of intellectual property rights, and combating counterfeiting and piracy (in liaison with ICC Commercial Crime Services).

The Commission has an *ad hoc* working party on the interface between IP, development and the protection of the environment chaired by Tim Roberts.

1.2.2.3. Position

The ICC takes a strong pro-IPR stance. It is ICC's position that:

- both the CBD and TRIPS are important international conventions, equally binding on their numerous signatories. They deal with different topics. They are fully consistent with each other and must both be fully implemented by their signatories;
- the CBD and the WTO TRIPS Agreement have both been ratified by an overwhelming numerical majority of United Nations members (though with the significant exception, in the case of the CBD, of the USA). On the face of it, therefore, the ICC believe it is unlikely that there should be significant conflicts between them;
- not only does TRIPS not contradict the CBD, but that, by promoting intellectual property protection, it in fact supports the CBD's objective;
- if any of the provisions of the CBD and the TRIPS agreement were found to conflict, it would be the TRIPS Agreement that takes precedence (Under the Vienna Law on Treaties, the agreement that is either later in time or clearer and more specific on the issue will control). In the case of the TRIPS Agreement and the CBD, both factors would result in the TRIPS Agreement taking precedence.

ICC maintains that the two conventions deal with different areas and are fully compatible with each other, both in spirit and in substance. However, should a conflict ever be found, ICC will argue strongly against weakening the existing provisions of TRIPS. The ICC firmly believes that the protection of intellectual property stimulates international trade and investment and encourages transfer of technology, which are all essential for economic growth.

The ICC supports maintaining, at this stage, the existing wording of Article 27.3(b). It believes that an initiative to re-open the debate on Article 27.3(b) is likely to give rise to the same controversies which surrounded the negotiations over the original clause, with the risk of endangering the advances made in this area. The ICC feels that the time is not yet ripe to call for a substantive change of the international rules in this field as in many countries existing TRIPS provisions have not yet, or have only recently, been implemented.

1.2.2.4. Overall influence and importance of activities

The ICC works closely with *inter alia* WIPO, the WTO and the AIPPI. For example, the ICC consults regularly with WIPO and at these meetings the ICC is usually represented by the Chairman of the

Commission and of the working party. The ICC also has consultative status at the highest level with the UN and its specialised agencies, and is very active with UNCTAD.

The consultation and working relationship with these important institutions has provided the ICC with a highly effective means of channelling business recommendations to political and institutional leaders.

1.2.3. The European Association for Bio-industries (EUROPABIO)

1.2.3.1. Structure and membership

EuropaBio represents 47 European bio-industries corporate members operating globally (both dedicated biotechnology firms and large corporations which use biotechnology as well as other technologies) and 12 national associations (totalling up to 700 SMEs) involved in research and development, testing, manufacturing and distribution of biotechnology products.

EuropaBio networks worldwide, forming part of (and serving as the headquarters for) the International Bioindustry Forum, which consists of the Japanese Bioindustry Association, the (US) Biotechnology Industry Organisation, and the Industrial Biotechnology Association of Canada. EuropaBio also provides the administrative base for the Forum for European Bioindustry Co-ordination, whose members comprise European industry sector federations (including EFPIA and CEFIC)⁴⁷.

1.2.3.2. Relevant activities

EuropaBio aims to be a promoting force for biotechnology and to present its proposals to industry, politicians, regulators, NGOs and the public at large⁴⁸. EuropaBio's mission is to:

- act as a catalyst for Life Sciences Business;
- improve the competitiveness of the European bio-industries;
- co-ordinate with all other parties involved;
- be active in all areas concerning biotechnology.

Europabio's key objectives are to:

- secure the establishment of appropriate regulation;
- develop coherent and supportive European and national policies for biotechnology;
- assure transparent, broad consultation and high standards of competence;
- encourage, engage and initiate full, open and informed public debate on biotechnology;
- establish an encouraging climate for biotechnology in Europe; and
- promote market authorisation for products.

To this end, EuropaBio has established several different Task Forces dealing on key issues. These include Patents, Bio-Safety, SMEs/Innovation and the 5th Framework Program and Competitiveness. Regulation and IPRs are key interests.

⁴⁷ For more information on EuropaBio, the FEBC and the IBF contact: EuropaBio, Avenue de l'Armee 6, B-1040 Brussels; tel: +32 2 735 03 13; fax: +32 2 735 4960.

⁴⁸ See Website: www.europa-bio.be

1.2.3.3. Position

EuropaBio takes the following position:

- patents promote transparency and innovation;
- the importance of patents and the protection they confer on innovative new products and processes is fundamental to the growth of European industry;
- new innovative products and processes generate new commercial opportunities and encourage entrepreneurship and new job opportunities;
- strong patents encourage investment in research and development and in manufacturing and marketing;
- patents renew the economy of society. SMEs and research-based start-up companies need, in particular, strong patents as incentives to initiate venture capital funding, to come to the stock markets and to raise funds for research programmes;
- the successful introduction of new medicines, new and improved foods, and improved ways of combating pollution will be achieved most effectively with sound patent law.

1.2.3.4. Overall influence and importance of activities

EuropaBio is supported by the expertise and collective influence of its hundreds of company members and a network of 12 national associations. EuropaBio works with regional, national and European policy and decision makers to foster a legislative and regulatory environment and releases information to enhance public awareness of the benefits, achievements and potential of the bio-industries.

1.2.4. International Federation of Pharmaceutical Manufacturers Associations (IFPMA)

1.2.4.1. Structure and membership

The IFPMA⁴⁹ represents the multinational research-based pharmaceutical industry and other manufacturers of prescription medicines, worldwide. The membership consists of over 56 national industry associations from both developed and developing countries. Corporate members include mainly research-based firms but also those which manufacture generic and non-prescription drugs.

IFPMA has a close working relationship with the European Federation of Pharmaceutical Industry Associations (EFPIA), Brussels, and EFPIA's 16 Member Associations are also members of IFPMA but the two federations are completely separate administrations. EFPIA deals with all matters concerning the relationship between the pharmaceutical industry and the Commission of the European Communities and the EC Directives which are concerned with prescription medicines.

1.2.4.2. Activities

The objectives of IFPMA are to:

- deal with questions of common interest (e.g. health legislation, science, research) to contribute to the advancement of the health and welfare of the peoples of the world;
- promote and support continuous development throughout the pharmaceutical industry of ethical principles and practices;

⁴⁹ 30 rue de St-Jean, PO Box 9, 1211 Geneva 18, Switzerland. Web site: www.ifpma.org.

- to contribute expertise to and co-operation with national and international, governmental or non-governmental, organisations with the same aims;
- co-ordinate the efforts of Members to meet these objectives.

IFPMA represents the interests of the international pharmaceutical industry through :

- fact-gathering and analysis of the policy issues of major importance to industry;
- advocating policies supporting intellectual property protection, market competition, drug regulation and access to information about new therapies;
- encouraging measures consistent with the objectives of industry and patients stated above;
- co-ordinating and leading member association and industry efforts to achieve an environment conducive to therapeutic innovation and competition.

Advisory Committees have been established on patent protection (Intellectual Protection Steering Committee), on health economics, (Health Economics Advisory Group) on public affairs (Public Affairs Committee) and on biological and biotechnological products (Biological Committee). *Ad hoc* groups are convened to undertake specific tasks, such as the preparation of publications and symposia.

The IFPMA has a Director of Intellectual Property and Trade Issues (Dr Noehrenberg), responsible for negotiations between the industry and the major international organisations involved in intellectual property and trade issues, including the WTO, the World Health Organisation (WHO), the World Bank and WIPO.

1.2.4.3. Position

In its position paper “Intellectual Property: Patents and Pharmaceuticals”, the IPFMA states that:

- the research-based pharmaceutical industry is highly dependent on intellectual property (IP), especially patent protection;
- without patent protection the world would have been deprived of the innovative pharmaceutical developments;
- patent protection for pharmaceuticals provides a broad range of benefits both to patients and to the economy;
- the TRIPS Agreement is to be welcomed; countries should therefore accelerate their implementation of TRIPS.

Furthermore in its paper “WTO Millennium Round”, the IPFMA argued that a full and complete implementation of the existing obligations of the TRIPS must take place. Concerning Article 27.3 (b), IFPMA did not take a position on whether or not IPRs should be included in a new trade round but recommended that if they were, the exception to patentability in Article 27.3 (b) should be removed.

1.2.4.4. Influence and importance

IFPMA has consultative status with many United Nations and other international organisations: it was admitted into official relations with WHO in 1971 and is also on the NGO roster for WIPO, UNCTAD, the United Nations Industrial Development Organisation (UNIDO), the United Nations Economic and Social Council (ECOSOC), the United Nations Children's Fund (UNICEF) and the Council of Europe. IFPMA is excluded from having representative status at the CBD, being seen as an interested party whose goals do not support the CBD.

1.2.5. European Federation of Pharmaceutical Industries and Associations (EFPIA)

1.2.5.1. Structure and membership

EFPIA represents the European pharmaceutical industry and has both national pharmaceutical industry associations and companies in its membership. It has a secretariat of some 30 persons and is governed by a General Assembly consisting of all full members and meeting at least once a year and a Board which has representatives from 11 member associations and 11 full member companies.

1.2.5.2. Activities

EFPIA sees its role as:

- providing close links and representing the industry's interests with policy-makers at European and international level;
- consulting and informing its members on European initiatives and developments affecting the industry;
- producing publications and organising other events to keep its target audiences informed.

EFPIA has three main policy committees dealing with economic and social policy; scientific, technical and regulatory policy and intellectual property policy respectively. On particular issues of concern the Board may propose the establishment of priority action teams chaired by a director of a member company.

1.2.5.3. Position

In its position paper 'TRIPS and the Millennium Round', issued in June 1999, EFPIA argued strongly for full and complete implementation of the obligations of TRIPS and noted that if TRIPS were to be included in a new WTO Round the mandate for negotiation 'must be clearly limited to improvements in the level of intellectual property protection'. These improvements were seen as necessary to encourage innovation, creativity and the global competitiveness of European R & D based companies. While no direct reference is made to Article 27.3 (b) it is stated that the potential exemption from patentability of plants and animals should be removed.

1.2.6. International Association for the Protection of Industrial Property (AIPPI)

1.2.6.1. Structure and members

The AIPPI⁵⁰ was founded in 1897. Its more than 8,000 members come from over 100 countries and consist of patent agents and attorneys, patent office staff members, company executives, academics and jurists. Most of the members are organised into National and Regional Groups. AIPPI is managed by a Bureau, while a Council of the Groups' Presidents and an Executive Committee of around 350 Delegates from the Groups execute the function of two "Houses of Parliament".

1.2.6.2. Activities

The objective of the AIPPI is to "improve and promote" industrial property (i.e. mainly patent and trademark) protection at international and national levels.

⁵⁰ AIPPI General Secretariat, Bleicherweg 58, Postfach, 8027 Zurich, Switzerland. Tel: +41 1 204 12 60; fax: +41 1 204 12 61.

The AIPPI conducts research on topical interests of concern to the industrial property communities. National Groups produce a report on each current issue, explaining what their current law is and indicating how they can envisage an international consensus developing on that issue. A Working Committee (where each National Group can be represented) draws on these reports in developing an AIPPI position on the issue, which can become a formal AIPPI Resolution. AIPPI supports representatives appointed from within its ranks to attend and participate actively in hearings and meetings organised by international and regional bodies (such as WIPO, WTO and the European Patent Office). AIPPI has regular high level contacts with international and regional institutions, including annual meetings with the Director-General of WIPO.

1.2.6.3. Position

AIPPI has not issued an official position on the CBD/TRIPS relationship. However, considering that the professions which many of its members belong to are associated with strong pro-IPR sentiments, it seems unlikely that any of AIPPI's research would reach any unconventional conclusions on this subject. Clearly, AIPPI has an interest in the development and expansion of IP law.

1.2.6.4. Influence and importance

AIPPI's Resolutions are supplied to WIPO, WTO and national patent and trademark offices around the world. Over 700 Resolutions have been passed by AIPPI. By those Resolutions AIPPI claims to have had a major influence on the development of international IPR law for over a century.

1.2.6.5. Overview of future developments in activities

AIPPI has had a long relationship with WIPO while its links with the WTO are more tenuous since it is competing for influence with a large number of other outside interests and has no privileged access. The AIPPI Report on the Seattle Ministerial Conference suggested a certain lack of confidence that it can influence the WTO in the way it has clearly managed to influence WIPO. The Report betrays the sentiment that the latter organisation's technical and specialised environment provides a more congenial milieu than the WTO's more politicised forum in which deal making may lead to outcomes that go against more technical approaches to improving the international IPR regime⁵¹.

1.2.7. International Association of Plant Breeders (ASSINSEL)

1.2.7.1. Structure

ASSINSEL is the International Association of Plant Breeders for the Protection of Plant Varieties. It is composed of 44 individual organisations involved in plant breeding spread over 31 developed and developing countries, which in turn represent more than 1000 companies worldwide. ASSINSEL works closely with the International Seed Trade Federation (FIS) with which it shares its secretariat.

ASSINSEL is governed by an Executive Committee. It is organised into six Crop Sections and three Working Groups, plus *ad hoc* committees which are appointed to meet special needs. The Working Groups are the Intellectual Property Group, the Committee on Sustainable Agriculture and the Communication Committee.

⁵¹ "There is a danger that WTO might tend to sacrifice the concept of systematic IP protection carefully built up and perfected in over 100 years of efforts in favour of pragmatic negotiated trade Rules."

1.2.7.2. Activities

The mission of ASSINSEL⁵² is *inter alia*:

- to represent at the international level and to promote through national organisations the interests of plant breeders and others who may share a common and active major interest in the creation of new plant germplasm;
- to establish and protect the intellectual property rights which follow from investments in such activities and to take all necessary steps to achieve these goals;
- to increase recognition of the importance and value of the plant breeders' contribution to world agriculture and horticulture.

ASSINSEL focuses primarily on issues related to the role of plant breeding in world agriculture, particularly with regard to creating and strengthening intellectual property rights for plant varieties developed and owned by its members. It also arbitrates between members in settlement of disputes relating to intellectual property rights or other plant breeders' interests.

1.2.7.3. Position

ASSINSEL believes that plant breeders' rights and patents are complementary. Both are considered to be important; the one does not render the other unnecessary. ASSINSEL would prefer that the 1991 Act of the UPOV Convention be considered to be *the sui generis* system: "The 1999 review of TRIPS Article 27.3b should not lead to any lessening of the protection required for plant varieties, though it might be useful to insert a specific reference to UPOV systems⁵³".

ASSINSEL accepts that UPOV-Plant Variety Rights are more appropriate for developing countries for the time being⁵⁴. Mainly this is because protected varieties remain in circulation for further breeding. However, at the June 1999 Congress, ASSINSEL recommended that developing countries adopt a *sui generis* system based on the 1991 Act of the UPOV Convention.

On access to genetic resources and benefit sharing, ASSINSEL in 1998 declared its preference for a multilateral system of exchange to counteract the restrictive nature of many bilateral agreements including all crops of interest to food and agriculture. The bilateral agreements which the CBD implicitly promotes favours countries rich in genetic resources and large companies, but not other interests. In return, ASSINSEL members would be willing to⁵⁵ "study a system in which the owners of the patents would contribute to a fund established for collecting, maintaining, evaluating and enhancing genetic resources. The mechanism for implementing that system would need to be discussed". Specifically, ASSINSEL has suggested two possible courses of action:

- that a new variety is protected by a UPOV system and is then made immediately available to everyone
- that if it is patented, the owner should pay a royalty to be paid into the multilateral system. The rate might be fixed in accordance with a material transfer agreement.

⁵² Chemin du Reposoir 7, 1260 Nyon; tel: +41 22 365 44 20; fax: +41 22 365 44 21; email: fis@worldseed.org (for FIS) assinzel@worldseed.org (for ASSINSEL)

⁵³ ASSINSEL (1999) Fostering plant innovation: ASSINSEL brief on review of TRIPS 27.3b.

⁵⁴ FIS and ASSINSEL (1998) Recommendations by the seed industry of developing countries on the revision of the International Undertaking.

⁵⁵ ASSINSEL (1998) Position on access to plant genetic resources for food and agriculture and the equitable sharing of benefits arising from their use (Adopted by the General Assembly in Monte Carlo on June 5, 1998).

1.2.7.4. Influence and importance

ASSINSEL was instrumental in the drafting of the original UPOV Convention and has continued to be the main international business association furthering the intellectual property and other interests of the seed industry. It is present as an observer at the negotiations on the IU.

1.2.8. European Chemical Industry Council (CEFIC)

1.2.8.1. Structure

CEFIC⁵⁶ represents, directly or indirectly, about 40,000 large, medium and small chemical companies in Europe. CEFIC is made up of the national chemical industry federations of 22 countries in Europe and large international companies which are members in their own right. The policy of CEFIC is determined by the General Assembly, the Board and the Executive Committee.

1.2.8.2. Activities

The objective of CEFIC is to provide a mechanism for structured discussion of issues affecting chemical companies operating in Europe and to represent the industry's position on these issues in order to contribute to the legislative decision-taking process.

The activity areas are health, safety and the environment, energy policy, science and education, competition policy, innovation policy, and trade and economics.

1.2.8.3. Position

In CEFIC's 1996 statement: "Patents: Key to Innovation in Europe", the organisation "welcomes the opportunity to co-operate fully on the Article 27.3 (b) TRIPS review to address issues affecting the chemical industry" including:

- "closing the loopholes which allow discrimination against certain products or processes (e.g. against plants and animals)"; and
- "ensuring that TRIPS is effectively addressed in the context of other international treaties, particularly the Convention on Biological Diversity."

In the October 1998 position paper on "TRIPS and the Environment", CEFIC argued:

- patents are the key to translating inventions into concrete developments and they provide the means to establish the necessary cycle of investment, research, innovation and re-investment;
- the TRIPS Agreement is a genuine advance for the world economy;
- it cannot accept any weakening of TRIPS in reply to unrealistic demands;
- there is no disharmony between TRIPS and the CBD;
- strong patent protection as required by TRIPS supports the objectives of the CBD.

As for Article 27.3(b), CEFIC says that the patentability of plants and animals should be made mandatory with inclusion of reference to the 1991 UPOV Convention as "the sole *sui generis* system."

⁵⁶ Avenue Van Nieuwenhuysse, 4 box 1B-1160 Brussels; tel: +32 2 676 7211; fax: + 32 2 676 7300; email general mailbox: mail@cefic.be.

1.2.8.4. Influence

CEFIC communicates and lobbies with a wide range of public bodies and official organisations, including UNCTAD, UNEP, FAO, WTO, OECD, WIPO. CEFIC has also developed a wide range of relations with other organisations representing the industry, such as the ICC and UNICE.

1.2.9. Novo Nordisk

1.2.9.1. Structure

Novo Nordisk is a trans-national life-science corporation with headquarters in Denmark. It is well known for its expertise in diabetes care. It is the world's largest producer of industrial enzymes, though it will spin off this business in the near future.

1.2.9.2. Activities and position

Amongst individual organisations which have sought to reconcile possible policy conflicts between TRIPS and the CBD, the Danish life-science corporation Novo Nordisk appears to be at the forefront.

Novo Nordisk, which is keen to position itself as a supporter of the principles of the CBD, issued an Environment and Ethics Report in 1998 containing a bio ethics section dealing with animal welfare, the CBD, patenting and the use of gene technology. ON IPR-related aspects of the CBD, the report states:

"Novo Nordisk will proactively contribute to the implementation of the objectives of the Convention. In order to do this we have formulated the following guiding principles, which we will do our utmost to live up to for all material covered by the CBD:

- no microbial strain or natural material obtained without proper prior informed consent from the country of origin will be included in screening;
- all materials screened should be covered by contracts and/or material transfer agreements;
- conditions should be on mutually agreed terms and should include benefit sharing, intellectual property rights and technology transfer arrangements where appropriate;
- contracts should be cleared by the proper authority in the country of origin;
- the country of origin will be mentioned in relevant publications *and patent applications*.

According to the company, this latter undertaking is already being implemented⁵⁷.

1.2.10. General business organisations' position and influence

1.2.10.1. Position

In general, industries dependent on patenting hold that there is no conflict between TRIPS and the CBD and favour the primacy of the former over the latter. For example, The ICC's Commission on Industrial and Intellectual Property statement on 28 June 1999: "TRIPS and the Biodiversity Convention: What Conflict?" refuted charges that TRIPS infringes the sovereignty rights of countries over their biological resources, encourages unsustainable use and promoted 'biopiracy'. The

⁵⁷ For more information on Novo Nordisk's policies, contact Hanne Gürtler, Manager, Microbiology, Health Care Discovery and Development, Novo Nordisk A/S, Novo Allé, 2880 Bagsvaerd, Denmark; tel: +45 4442 2305; fax: +45 4498 3622; email: hg@novo.dk.

statement concludes that the two conventions deal with different areas and are fully compatible with each other, both in spirit and in substance. However, should a conflict ever be found, ICC will argue strongly against weakening the existing provisions of TRIPS.

The industry is also concerned that the existence of the CBD and its provisions on national sovereignty and equitable benefit sharing may be used as pretexts to weaken the provisions of TRIPS, and are anxious for developing countries to implement TRIPS in full and as soon as possible. For the industry as a whole, biodiversity is generally a relatively remote issue with there being very little interest in the IU.

The pharmaceutical industry is the most dependent on strong patent protection. TRIPS was a major undertaking in their efforts to strengthen patent protection in many areas of world where it was ineffective. It came against a long history of denial of patent protection in pharmaceuticals – in product or process of manufacture. This industry will lobby against changes that weaken TRIPS. They are adamant that biodiversity must not be used as excuse to renegotiate TRIPS, and that there is no need to carve out separate provisions for generic resources in developing countries.

The position of seed trade associations and independent seed companies varies somewhat from the chemical/pharmaceutical/biotech industries. Seed firms, many of which are being bought up by the latter types of company, tend to have a stronger concern that the supply of genetic resources from developing countries is maintained, and feel threatened by the CBD's emphasis on national sovereignty and access/benefit sharing regulation. The seed industry position is also that there is no conflict between the TRIPS and the CBD agreements.

1.2.10.2. Influence

The industry lobbies have been able to dominate international IPR regulation since IPRs were inserted into the Uruguay Round agenda in the late 1980s. A number of observers argue that the industry lobby groups essentially wrote the TRIPS Agreement, especially the US industry and a narrower group in the EU. They came from a combination of sectors with the pharmaceuticals, US motion pictures and software companies leading the way. In developing countries these industry groups operated through Associations of Patent Lawyers. These formed a group that pressed for higher standards of IP and have strong ties to pharmaceutical groups. The biggest threat to their position is felt to lie in the possibility that developing countries will conclude that they are net losers from the WTO TRIPS rules and either succeed in weakening those rules or even withdrawing from the WTO.

The different business organisations collaborate to promote their shared interests, and quite a number of individuals are members of – and may hold a senior position in – more than one of these associations⁵⁸. Business lobbies use a mixture of approaches to influence events and work in the major developed and developing countries ministries, in Geneva and elsewhere where negotiations take place. Work in capitals to set the negotiating agenda of major players appears to be the most effective route for influence.

1.3. Non-business NGOs

As with business associations, NGOs working in the general area of intellectual property rights and biodiversity vary in how far these issues are central to their concerns or are among a wide range of

⁵⁸ For example, Josef Straus, Head of Department at the Max Planck Institute is also Chairman of AIPPI's Programme Committee.

topics with which they deal. This section starts with those international NGOs dealing specifically with IPRs and biodiversity (such as GRAIN and RAFI), and then proceeds to other organisations that are also actively engaged in international debates in these areas but have much wider interests (for example, environmental NGOs). Most (international) NGOs are headquartered in the North but there are a number of organisations – both those set up by indigenous peoples/local communities, and others by more urbanised groups – that are based in developing countries but are also transnational. As with business associations, many of these groups network and collaborate, and exchange information frequently through the Internet.

There are a large number of NGOs involved to a lesser or greater extent in issues related to IP and biodiversity. In this section, we provide details on the majority (though not all) of the key NGOs involved in these issues.

1.3.1. Genetic Resources Action International (GRAIN)

1.3.1.1. Structure and activities

GRAIN is an international NGO set up in 1990 to mobilise international action against genetic erosion. Its headquarters are in Barcelona⁵⁹, but it has an office in the Philippines from where it disseminates information on the Internet through its BIO-IPR list server. It also publishes position papers, briefing notes, a regular newsletter (“Seedling”), books, and undertakes workshops.

The organisation is governed by a Board composed of scientists, grassroots field workers, development NGOs and policy makers from various countries acting in their personal capacity. GRAIN is financed by grants from NGOs, governments and intergovernmental organisations.

GRAIN works to help strengthen farmers' and local communities' control over agricultural biodiversity, especially in developing countries. Their programme covers: the impact of trade liberalisation on biodiversity, countering the spread of intellectual property on life, strengthening community rights, and monitoring agricultural research systems. GRAIN pursues its aims by promoting local control over agro-biodiversity, supporting community-based sustainable agricultural programmes, and opposing the environmental harm caused by industrial agriculture.

1.3.1.2. Position

GRAIN is fundamentally against the patenting of all life-forms and their structural and function components. In their paper “For a full review of TRIPS 27.3 (b)”, released in March 2000, GRAIN argues that the proposals advanced by many South governments (such as the Africa Group), should be put into action, namely:

- a thorough review of the provisions of Article 27.3(b);
- an extension of the transition periods;
- the resolution of outstanding issues such as the call to clarify that life forms should not be patentable.

1.3.1.3. Influence

GRAIN exerts its aims, ideas and position in several ways:

⁵⁹ Girona 25, pral., E-08010 Barcelona, Spain. Tel: +34 93 3011381; fax: +34 93 3011627. <http://www.grain.org/about.htm>

- through its BIO-IPR listserver, which circulates information about developments in the field of intellectual property rights related to biodiversity and associated knowledge;
- actively lobbying at international fora for the collective/community rights of farmers, indigenous peoples, fisherfolk and others, and against the privatisation of biodiversity through patents;
- working with organisations at the national and regional levels which advocate for control over local resources and associated knowledge;
- promoting open and relevant national research systems that work closely with farmers.

1.3.2. Rural Advancement Foundation International (RAFI)

1.3.2.1. Structure and activities

RAFI is an international NGO and has offices in Canada and the United States⁶⁰. RAFI works primarily at the global and regional (continental or sub-continental) levels. In its own words, the organisation⁶¹:

"is dedicated to the conservation and sustainable improvement of agricultural biodiversity, and to the socially responsible development of technologies useful to rural societies. RAFI is concerned about the loss of genetic diversity - especially in agriculture - and about the impact of intellectual property on agriculture and world food security".

RAFI is funded by a number of national governments (such as Canada, Germany, the Netherlands and Sweden) and international institutions (such as the IPGRI, the FAO). RAFI works in partnership with NGOs for co-operative and sustainable self-reliance within rural societies, through the provision of information on socio-economic and technological trends and alternatives. RAFI's strength is in the research and analysis of technological information (particularly but not exclusively plant genetic resources, biotechnologies, and biological diversity), and in the development of strategic options related to the socio-economic implications posed by new technologies.

1.3.2.2. Position

As with GRAIN, RAFI is opposed to patenting life. It also opposes *all* bioprospecting on the grounds that without the appropriate regulatory protection for indigenous peoples being in place anywhere, bioprospecting is essentially synonymous with 'biopiracy', a terms which RAFI also introduced to the NGO lexicon. RAFI tends to the view that developing countries have provided the bulk of the genetic resources that are currently 'in circulation' (i.e. available in public collections) and should therefore be recompensed for this contribution. IPRs are considered to exacerbate the unequal distribution of benefits between the North and the South while at the same time encouraging and even legitimising the exploitation of traditional knowledge.

1.3.2.3. Influence

RAFI is considered to be tremendously effective in dissemination of information. To increase effectiveness and influence, RAFI undertakes joint actions with other NGOs (such as GRAIN and GAIA) at the regional and global level.

⁶⁰ Pat Roy Mooney / Bev Cross. RAFI Headquarters, 110 Osborne St., Suite 202, Winnipeg MB R3L 1Y5, Canada. Tel: 1 204 453-5259; fax: 1 204 925-8034. Jean Christie / Julie Delahanty, RAFI, 180 Argyle St., Suite 310, Ottawa ON K2P 1B7, Canada. Tel: 1 613 567-6880; fax: 1 613 567-6884. Hope Shand, RAFI, 118 E Main St. Room 211, Carrboro NC 27510-2300, USA. Tel: 1 919 960-5223; fax: 1 919 960-5224.

⁶¹ see <http://www.rafi.org>

RAFI is generally felt to be influential in debates especially at the IUPGR level, where it attends the negotiating sessions. As an awareness-raising organisation, RAFI is perhaps the most influential of all NGOs in this field. The director of RAFI, Pat Mooney, not only coined the Farmers' Rights concept⁶² but then lobbied developing country governments so successfully that Farmers' Rights – although still vaguely elaborated and remaining to be implemented nationally or internationally – has been one of the major issues for discussion at the FAO's Commission on Genetic Resources for Food and Agriculture for well over a decade. It is viewed with considerable hostility by some in the business area.

1.3.3. Third World Network (TWN)

1.3.3.1. Structure and activities

The TWN is an international network of organisations and individuals involved in issues relating to development, the Third World and North-South issues. Its objectives are *inter alia* to conduct research on economic, social and environmental issues pertaining to the South; and to provide a platform representing broadly Southern interests and perspectives at international forums such as the UN conferences and processes.

The TWN's international secretariat is based in Penang, Malaysia, but there are offices also on most continents. It also has many affiliated organisations, and co-operates with several organisations in the North, such as the GAIA Foundation.

1.3.3.2. Position

Its positions on TRIPS and the CBD are very close to those of these other Northern-based NGOs. TRIPS is seen as an imposition on the South which primarily benefits transnational corporations. As with other organisations, condemnation is focused almost exclusively on the patents section. The CBD is considered to provide opportunities to defend the sovereign rights of developing countries as well as indigenous and local communities.

1.3.3.3. Influence

The Third World Network is a highly influential international organisation including in the TRIPS and CBD spheres. It is considered as the most important NGO in the South on the issue of TRIPS and biodiversity. Third World Network enjoys the added legitimacy of being an authentic developing country organisation.

The TWN's Community Intellectual Rights Act (CIRA) of 1994 was one of the earliest comprehensive efforts to develop model *sui generis* national legislation that would give communities property-style rights of control over their collective knowledge. The Act addresses many of the issues that continue to challenge current efforts to develop laws to protect indigenous and local knowledge.

The Act was an early and influential attempt to begin framing ways in which indigenous and local knowledge could be treated in national *sui generis* intellectual property laws. For example, in March 1998, the Scientific, Technical and Research Commission of the Organisation of African Unity (OAU/STRC) task force on community rights and access to biological resources met to develop a draft

⁶² And also 'biopiracy' and 'terminator technology'.

model legislation on community rights and access to biological resources as a basis for national legislation and an Africa-wide convention. This draft model law was based on TWN's CIRA. In June 1998, a summit of OAU heads of state recommended that member governments *inter alia*: "adopt the draft Model Legislation on access to biological resources and call on Member States to initiate the process at national level involving all stakeholders in accordance with national interest and enacted into law."

1.3.4. Institute for Agriculture and Trade Policy (IATP)

1.3.4.1. Structure and activities

The IATP⁶³ was established in 1986 in the USA. Its mission is to create environmentally and economically sustainable communities and regions through sound agriculture and trade policy.

The Institute assists public interest organisations in effectively influencing both domestic and international policymaking through monitoring, analysis and research; education and outreach; training and technical assistance; and coalition building and international networking.

1.3.4.2. Position

IATP appears to subscribe to similar analyses to RAFI, GRAIN and Gaia, but with less stridency.

1.3.4.3. Influence

IATP is a very active NGO working on agriculture and trade issues relevant to the interests and well-being of consumers, farmers and farming communities in the United States and internationally. It has been very active in Geneva, engaging with missions to put over its point of view and supporting a major workshop on 27.3(b) in November 1998, in cooperation with the South Centre, which did much to raise awareness of these issues with developing country delegates to the WTO

1.3.5. The Indigenous Peoples' Biodiversity Network (IPBN)

1.3.5.1. Structure and activities

The IPBN⁶⁴ is an association of indigenous peoples and indigenous peoples' organisations working towards the common goal of nurturing biological diversity for the benefit of indigenous communities and humankind as a whole. The IPBN was established by indigenous peoples who acted as observers at the first meeting of the Intergovernmental Committee on the Convention on Biological Diversity (ICCBD) in October 1993.

The IPBN is active in issues of indigenous knowledge, intellectual property and benefit sharing and works closely with indigenous communities around the world to strengthen their capacity to maintain and benefit from their own knowledge, innovations and practices, which includes having a voice in national, regional and international policy development. IPBN works in the formulation of policies, laws and programmes relating to biodiversity and protection of traditional knowledge. IPBN from time to time advises the CBD Secretariat on Article 8 (j)-related matters in an informal capacity.

⁶³ 2105 First Avenue South, Minneapolis, MN 55404-2505; tel: +1 612 870 3400/3405/3411; fax: +1 612 870 4846. <http://www.iatp.org>.

⁶⁴ Alejandro Argumedo, Indigenous Peoples' Biodiversity Network, PO Box 567, Cusco, Peru; tel: +51 84 232 603; fax: +51 84 245 021; email: ipbn@web.net

1.3.5.2. Position

Like most indigenous peoples' organisations, the position of IPBN is that recognition of the right to self-determination is the most important claim and the one shared by indigenous peoples worldwide. IPBN also emphasises the need to recognise and respect indigenous customary law especially relating to management of biodiversity and indigenous peoples' intellectual property. Like all the above organisations, IPBN condemns the global IPR trends as leading to ever stronger protection over life-forms, and biopiracy.

1.3.5.3. Influence

. IPBN and other indigenous peoples' organisations have been quite effective in using the CBD as a forum to get their views across to governments. It is largely through the lobbying of these organisations that the *Ad hoc* Working Group was established and the agreement was made to employ an indigenous person at the Secretariat as a liaison officer. They have been less active in the IUPGR negotiations and have had a relatively minor influence on WTO processes, except that the recent proposal to the General Council on traditional knowledge made by a number of South American countries was almost certainly the result in part of lobbying by indigenous peoples' organisations such as IPBN. The COP is an open forum where indigenous people can lobby delegates directly. Moreover, indigenous people have occasionally been invited onto national delegations participating at COP and other meetings held under CBD auspices.

1.3.6. ACTIONAID

1.3.6.1. Structure and activities

ActionAid⁶⁵ is a British charity dedicated to helping alleviate poverty in the more than 30 countries in which it works. It campaigns *inter alia* against both the introduction of genetically-modified crops and also the patenting of basic food crops.

1.3.6.2. Position

ActionAid opposes patenting life essentially on the grounds of threats to the livelihoods of the poor and to food security. In November 1999, ActionAid produced a well-publicised report called "Crops and Robbers: biopiracy and the patenting of staple food crops". The report advocates that:

- the WTO [must] support an amendment to Article 27.3(b) of TRIPS provisions that would enable WTO members to exclude all genetic resources for food and agriculture from the agreement;
- the members of the WTO recognise the primacy of the CBD over TRIPS. CBD gives national states sovereign rights over their biological resources and allows the protection of indigenous knowledge and rights;
- governments introduce a five year freeze of patenting in food and farming until the socio-economic and environmental impacts can be evaluated;
- companies who hold patents which could be used to substitute southern crops to confirm that these patents will not be commercialised in this way;
- companies involved in patenting staple food crops place that information into the public domain. Publicly-funded human genome mapping projects have signed an accord to this effect, and

⁶⁵ Hamlyn House, MacDonald Road, Archway, London N19 5PG, UK. Tel: +44 20 7561 7561; fax: +44 20 7272 0899; email: mail@actionaid.org.uk

negotiations are afoot for a US/UK “joint high-level statement of support”. [We believe] a similar accord should be signed to promote public research into the staple food crops.

1.3.6.3. Influence

Actionaid has influence at both the national UK level and internationally in the countries in which it works through its Food Rights Campaign. It works both as a lobbyist and public campaigning organisation. Action Aid is chair of NGO trade network in the UK – network members meet regularly with the UK Department of Trade and Industry (DTI) and government officials, sometimes with desk officers, sometimes with Director General trade policy, sometimes with Ministers. It was one of the NGOs regularly briefed at Seattle by UK Ministers.

1.3.7. Centre for International Environmental Law (CIEL)

1.3.7.1. Structure and activities

The Centre for International Environmental Law⁶⁶ (CIEL) is a public interest, not-for-profit environmental law firm founded in 1989 to strengthen international and comparative environmental law and policy around the world. The organisation’s main office is in Washington, but it has also had an office in Geneva since 1995. The Geneva office was set up to focus on the WTO and to liaise more effectively with other Geneva-based NGOs.

CIEL’s goals are to:

- solve environmental problems and promote sustainable societies through the use of law,
- to incorporate fundamental principles of ecology and justice into international law,
- to strengthen national environmental law systems and support public interest movements around the world, and
- to educate and train public-interest-minded environmental lawyers.

Two of its programme areas are Biodiversity and Wildlife, and Trade and Environment.

CIEL provides a full range of environmental legal services in both international and comparative national law, including: policy research and publication, advice and advocacy, education and training, and institution building. Other activities include capacity building and training, and publishing on environmental law.

Its influence extends partly through CIEL’s as a law firm for the environmental community and advisor to non-governmental and inter-governmental organisations. Recently, CIEL assisted COICA in its opposition to the ayahuasca patent by compiling and filing a re-examination request with the US Patent and Trademark Office

1.3.7.2. Position

CIEL has produced papers for the CBD Secretariat for discussion at meetings of the COP and SBSTTA, including on IPRs and is currently producing a paper for the WWF. It has recently released

⁶⁶ CIEL (United States), 1367 Connecticut Avenue, NW Suite #300 Washington, DC 20036, USA. Tel: +1 202 785-8700; fax: 1 202 785-8701; email: info@ciel.org. <http://www.ciel.org/reciel.html>
 CIEL (Switzerland), B.P. 21 160a Route Florissant, CH-1231, Conches, Geneva, Switzerland. Tel: +41-22-789-0738; fax: 41-22-789-0500; email: cielgva@igc.org

a discussion paper entitled “The TRIPS Agreement, sustainable development and the public interest” in conjunction with the World Conservation Union (IUCN). This critically examines the TRIPS Agreement in the context of the trade negotiations in December 1999 and beyond. It locates the Agreement within the ongoing debate concerning the nature and purpose of IPRs, with a focus on IPRs covering technology such as patents. It reviews some of the potential impacts of IPRs:

- on the innovation of technology
- on the dissemination of technology;
- on consumer access to health;
- in the field of biotechnology; and
- on the Convention on Biological Diversity.

The review suggests that the potential for the Agreement to meet its objectives is at best unclear. As a result, policy-makers should avoid any further expansion of IP protection under the WTO at this time.

1.3.7.3. Influence

CIEL is not a campaigning NGO but lays out issues and options. Generally, CIEL does not propound political positions, but it makes reasoned proposals based on analyses which tend to be more even-handed and rigorously argued than some of the other NGO actors.

1.3.8. The GAIA Foundation⁶⁷

1.3.8.1. Structure and activities

The organisation, based in London, was founded in 1984 to raise public awareness about threats to the biosphere resulting from the loss of both cultural and biological diversity. GAIA Foundation acts not just as an independent actor with its own positions on key issues, but is a facilitator that responds to the need for capacity-building in developing countries.

It networks with other organisations there, helping them to secure both financial and political support for their work. It does not provide funds for developing country organisations and networks itself, but channels them to where they are needed. Among the important NGOs in the North and South with which GAIA collaborates are Third World Network and GRAIN.

1.3.8.2. Position

The GAIA Foundation holds strong positions with respect to intellectual property rights. IPRs are viewed essentially as economic rights that are hostile to the interests of people in the South, especially indigenous peoples and traditional communities. Patents and UPOV-Plant Variety Rights are both condemned for providing critical support for the industrial agricultural systems which damage biodiversity and erode the rights of the poor.

The GAIA Foundation is also concerned about the effects of trends in patenting life in the health sphere. This trend is considered to be contrary to the public interest by distorting research priorities and inhibiting socially useful innovation.

⁶⁷ The Gaia Foundation, 18 Well Walk, Hampstead, London, NW3 1LD, UK. Tel: +44 171 435 5000; fax: +44 171 431 0551.

1.3.8.3. Influence

The GAIA Foundation is widely considered to be a key actor in international debates on the CBD and TRIPS relationship, and is viewed as an aggressive campaigner. GAIA has financed delegates for workshops and organised regional workshops in Africa. GAIA also finances some African delegates to the IUPGR and is influential in Ethiopia.

1.3.9. Greenpeace

1.3.9.1. Structure and activities

Greenpeace is an international environmental NGO known for its policy of peaceful direct action. It is campaigning in various ways against genetic modification of crops and patenting of life generally, including legal action against specific patents.

1.3.9.2. Position

Greenpeace categorically opposes patenting life. The main reasons seem to be environmental concern, bioethics, biopiracy and oligopolistic market control in agribusiness, especially in developing countries.

1.3.9.3. Influence

One important means by which Greenpeace has influenced European policy concerning patents on living things is to legally oppose specific patents at the EPO. Greenpeace was involved in a landmark case in 1995 (Greenpeace v Plant Genetic Systems NV) when the EPO Technical Board of Appeal ruled that a claim for plant cells contained in a plant is unpatentable since it does not exclude plant varieties from its scope. As a consequence, for the next four years plants remained unpatentable in Europe. The main grounds for opposition were that the invention would lead to increased use of herbicide and that releasing GMOs entailed unacceptable environmental risks. This year Greenpeace filed an opposition with the EPO to the University of Edinburgh's European patent for a process for the genetic manipulation of stem cells and embryos which could cover cloned humans. In this case, bioethics is apparently the main area of concern. Greenpeace was for over a period of about 10 years also a key member of an NGO campaign against the EU biotechnological inventions directive.

1.3.10. International Institute for Sustainable Development (IISD)

1.3.10.1. Structure and activities

The IISD is an independent policy research institute based in Canada with a European office in Geneva. The IISD mission is to champion environmentally sustainable innovation, enabling societies to live sustainably. It receives financial support from the government of Canada and other governments, UN agencies, foundations and private sector.

IISD contributes to sustainable development by advancing policy recommendations on international trade, economic instruments, climate change and natural resource management. It reports on international negotiations and brokers knowledge gained through collaborative projects with global partners, resulting in more rigorous research, capacity building in developing countries and a better dialogue between North and South.

1.3.10.2. Position

The IISD argues that TRIPS should be opened up, in the shape of an implementation peace clause for developing countries or an extension of the implementation period.

Unlike most NGO, which assume that IPRs are inherently unfair to developing countries and focus on problems in recognising traditional knowledge and furthering the interests of technology importing nations and consumers etc. IISD is not opposed in principle to IPRs as long as they represent genuine efforts to strike a balance where innovation is appropriately rewarded for its contribution to the public good. Though TRIPS shifted the balance too far in favour of the property owners, IISD believes that IPR protection can be consistent with the provision of environmental benefits. However, the IISD favours the objectives of CBD in relation to IP and support efforts to protect knowledge of biodiversity and incentives provided for that purpose. Furthermore, IISD favours the developing country and NGO pressures to change TRIPS, as a balance against the private industry and pro-trade community which tends to hold TRIPS as being almost sacrosanct.

1.3.11. World Wide Fund for Nature (WWF)

1.3.11.1. Structure and activities

The World Wide Fund For Nature⁶⁸ is the world's largest and most experienced independent conservation organisation, with around 5 million supporters and a global network of 27 National Organisations (mainly in Europe) , 5 Associates, and 21 Programme Offices.

The WWF global network is active in 96 countries, and combines science-based, solution-oriented conservation projects and policy work with capacity building and environmental education. WWF's mission is to conserve nature and ecological processes by:

- preserving genetic, species, and ecosystem diversity;
- ensuring that the use of renewable natural resources is sustainable both now and in the longer term, for the benefit of all life on Earth;
- promoting actions to reduce to a minimum pollution and the wasteful exploitation and consumption of resources and energy.

WWF's fundamental aim is to preserve the world's biological diversity, and it concentrates 80% of its activities on three priority areas on which the majority of life depends: forests, freshwater ecosystems, and oceans and coasts. To further focus its efforts, WWF has identified some 200 regions - the Global 200 - which are the best representatives of this diversity.

1.3.11.2. Position

Concerning TRIPS and biodiversity, WWF has made the following statements:

- modify existing systems of IPRs to protect public interest and to acknowledge previously unrecognised rights and/or reflect long term or collective processes of creation and structures of ownership of traditional knowledge;
- expand TRIPS Article 27.3(b) exclusions to include micro-organisms and microbiological processes;

⁶⁸ www.panda.org

- amend TRIPS to make it more responsive to biodiversity protection and equitable benefit sharing
- extend the phase in period for developing countries and LDCs since they need more time to build capacity and knowledge so that they may create IPRs and *sui generis* systems that are responsive to, and do not distort, their developmental, environmental and social priorities.

1.3.11.3. Influence

WWF has a global presence, and can take national initiatives that can be brought to the for a in Geneva. It has produced papers that have been widely used by those involved in the international negotiations.

1.3.12. QUNO

1.3.12.1. Structure and Activities

QUNO in Switzerland is one of two UN offices of the Religious Society of Friends (Quakers). It is long established and its representatives are well-respected in Geneva. It took up work on TRIPS following work by Quaker Peace and Service in the UK in its Environmental Intermediaries Programme on genetic resources. This had sought to support capacity building with Southern African countries in the negotiations on the IU. The focus of this work switched to WTO and the TRIPS Agreement, especially 27.3(b), and this became the responsibility of QUNO.

It has been facilitating developing country governments and specialists/facilitators to come together to explore the issues, but has not included NGOs and industry in this so far. It circulated widely a discussion paper laying out issues involved, had it translated into French and Spanish, and has hosted a series of lunches for developing country missions and two overnight retreats on different aspects of 27.3(b).

1.3.12.2. Position

It does not take a position on the substance of the debate but is initially concerned to strengthen the capacity and understanding of those who have been disadvantaged in the process of negotiations. It seeks to address the causes of conflict in all areas. It expects to draw in a wider range of interests into those discussions as time goes on.

1.3.12.3. Influence

It is widely regarded in Geneva as having had a considerable influence on the level of debate and development of positions on these issues in the international community at WTO.

1.3.13. General NGOs position and influence

1.3.13.1. Position

NGOs are responding to and seeking to influence international agreements like the CBD, TRIPS and the IUPGR. Their various approaches include:

- actively opposing trends in intellectual property and international trade law, especially the patenting of life-forms;

- advocating equitable benefit sharing from biotechnological research through use of model laws, local/traditional knowledge databases, contracts, or ethical guidelines and codes of practice, and intellectual property rights;
- using emerging international environmental and human rights law as part of a campaign aimed at empowering traditional communities.

What unites most of the efforts of these groups outside is the desire simultaneously to recognise the collective aspect of indigenous and local community stewardship and to provide those communities with different forms of control (ranging from restrictive to exclusive) over their knowledge. Naturally these organisations vary somewhat in their perspectives on such issues as neo-liberal economic policy and intellectual property rights. One interesting contrast can be found in the discourse used by those developing country NGOs that represent the interests of the Third World and the language used by indigenous peoples' organisations. While indigenous peoples' organisations almost incessantly demand recognition of their peoples' right to self-determination, pro-Third World NGOs such as Third World Network rarely if ever make such an assertion. Moreover, these latter groups tend to eschew use of the word 'property' in the indigenous/local community context either for ideological or strategic reasons. Indigenous peoples find western configurations of intellectual property highly problematic, but do not find the word 'property' inapplicable to their own societies since they do not treat it as synonymous with absolute ownership.

A number of the principal NGOs share a common stance on several issues. GRAIN, GAIA Foundation, and RAFI share a number of political positions on IPRs and biodiversity, such as opposition to 'patenting life' and what they regard as the excessively dominant market power of transnational corporations involved in the agribusiness, pharmaceutical and biotechnology industrial sectors. Both GRAIN and GAIA were actively involved in campaigning against the EU directive on biotechnological inventions. Both have also been sharply critical of the UPOV Convention, which they regard as being an unsuitable IPR system for developing countries.

Some of these organisations are working to develop community and collective rights regimes for farmers and indigenous peoples that are distinct and separate from intellectual property regimes. Many of these efforts predate the WIPO initiative. The best known example is probably TWN's CIR Act referred to above. NGOs from 19 countries also met in Thailand in late 1997 to explore the development of *sui generis* rights that aim to recognise and protect community innovation, and also nurture sustainable food and health systems. The Thammasat Resolution that emerged from that meeting asserts that *sui generis* rights are community and collective rights that are fundamentally different from the intellectual property-based *sui generis* systems promoted by the TRIPS Agreement.

1.3.13.2. Influence

The NGOs critiques, position papers and lobbying activities are directed at national governments in developing and developed countries and at all the major intergovernmental forums. GRAIN and RAFI for example have invested heavily in the FAO-IUPGR process, and appear to favour the FAO Commission as being the forum where the most favourable results are likely to be achieved. In contrast, quite a number of other groups, especially the indigenous peoples organisation, see the CBD processes as more promising arenas.

As a group, the NGO community plays an important role in the debate of TRIPs and biodiversity. NGOs have become increasingly better at understanding the complex issues involved and have become influential in setting the agenda on important issues. NGOs are acknowledged to have

instilled in developing countries a greater confidence in raising issue in TRIPS, for example on 27.3(b).

Campaigning by NGOs has also helped to make developed country governments more modest about what they want from TRIPS-related negotiations. Industrialised countries and industry lobbies are these days on the defensive, wanting to preserve what they have, rather than seek more. This is to a large extent due to the activism of the NGOs. Industrial lobbies fear that their own governments may make concessions in trade negotiations which go against their interests in order to placate the environment lobby.

SECTION B

2. Linkages between IPRs and biodiversity-related issues

As Section A shows, many different actors have a wide variety of views about IPRs and biodiversity. They disagree about the philosophical basis, the relative costs and benefits of the new (legal) framework developing in this area, and the long-term effects.

In this section we look at the linkages primarily from a legal viewpoint and secondly from a practical policy perspective. We have attempted to draw out from the differing views the key elements that distinguish them. We have grouped them under a number of headings to allow for a clearer debate about the policy options that need to be considered to strike a suitable balance among the conflicting interests.

Three agreements are central to the relationship between IPRs and biodiversity – TRIPS, CBD and IU. Our legal assessment is principally based on a comparison of the legal texts of the two major agreements dealing with IPRs and biodiversity, the TRIPS Agreement and the CBD, plus a third agreement still under negotiation, the IU. The IU is being renegotiated in harmony with the CBD, to regulate access and benefit-sharing specifically for plant genetic resources for food and agriculture. For the practical and policy assessment we draw to an important extent on the large and growing body of literature produced by the many actors in this area (described in Section A of this report) and extensive interviews with a broad range of people closely involved in this area (see Appendix 1 for a list of those interviewed). These interviews were conducted on an unattributable basis and comments arising from them will not be cited, except in a general way (for example, NGO business organisation, etc) so as not to identify the source.

2.1. The legal relationships

2.1.1. The multilateral legal context of trade and environment

There are probably some 900 multilateral or bilateral international legal instruments concerning the environment⁶⁹. At the end of the Uruguay Round of the GATT all signatories agreed to “identify the relationship between trade measures and environmental measures in order to promote sustainable development” and “to make appropriate recommendations on whether modifications of the provisions of the multilateral trading system are required, compatible with the open, equitable and non-discriminatory nature of the system”. The complexity of the trade and environment regimes means that the relationship between them will be worked out on a case by case basis.

2.1.2. CBD and TRIPS – legal conflicts

The relationship between TRIPS and the CBD has become a major focus of discussion in international policy circles. Some argue that they are incompatible, while others that there is no conflict. Business organisations⁷⁰ and patent experts such as Grubb, for example, claim that there is no conflict between the two: “The CBD deals with a body of law separate from that which is the subject of TRIPS, and in the areas in which they come in contact, primarily Articles 16 and 19 of the CBD, account is taken of the distinct nature of IP rights”⁷¹. Others see it as an open question. The Nuffield Council in a recent

⁶⁹ B. Boer, ‘The Globalisation of Environmental Law: The Role of the United Nations’ 20 1995 *Melbourne University Law Review*, 101.

⁷⁰ See Section A sub-section 2.2 on International Business Associations.

⁷¹ P.W. Grubb, *Patents For Chemicals, Pharmaceuticals and Biotechnology*, OUP, 1999, 47-48.

report recommended that the “UK in consultation with like-minded developing countries and other member states of the EU, propose that the WTO explore and report on the extent to which international and national legal frameworks currently frustrates the objectives of the CBD in providing fair and equitable access to genetic resources and how this conflict might be addressed”⁷². Yet others, particularly in the NGO community, see a clear conflict between the agreements⁷³.

The claim that there is a conflict between the CBD and TRIPS can, in part, be clarified by drawing a conceptual distinction between legal and policy conflicts. Laws rarely conflict in the sense of two rules contradicting one another. Similarly, legal principles which are more abstract than rules can stand in tension with one another, that tension being resolved through a process of interpretation. The principle of national sovereignty over genetic resources in the CBD, for example, might on the face of it seem to be in tension with the principle in TRIPS that intellectual property rights are private property. This kind of tension, however, can be accommodated through a process of ordering and interpretation. In British real property law, for example, the Crown is the ultimate owner of real property, but this has not stopped the recognition and evolution of rights of private property in land. But the absence of legal conflict does not signal that there is no policy conflict. For example, most governments in the world regulate the consumption of drugs and alcohol in a way that allows their citizens to consume those drugs while at the same time enacting policies that warn or even discourage citizens from doing so. Policies can and regularly do conflict in the absence of legal conflict (the potential policy conflicts are reviewed in sub-section 2.2 below).

2.1.2.1. Treaty objectives

a) *The CBD*

Three objectives are stated in Article 1 of the CBD⁷⁴:

- The conservation of biological diversity.
- The sustainable use of its components.
- The fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.

The terms biological diversity, sustainable use and genetic resources are all defined as well as many other terms used in the CBD (see Appendix 2 for details). Biological diversity refers to the variability of organisms, sustainable use refers to the use of that diversity in a way that does not lead to its long term decline and genetic resources refers to genetic material that contains functional units of heredity. The CBD covers three “levels”: genetic resources; species, and ecosystems. All are of actual or potential use or value for humanity. There is no suggestion in the text that any of one of the stated goals of the CBD is more important than another. However, different stakeholders focus on different levels. For ecologists, the species and ecosystem levels are the most important. For bioprospecting (that is, the pharmaceutical industry), chemicals of medicinal value identified in individual species are the target. For food and agriculture, the portfolio of agricultural species developed throughout the world (intra-specific genetic resources) is of prime importance: it is the raw material for plant and animal breeding.

⁷² Nuffield Council on Bioethics, *Genetically Modified Crops: The Ethical and Social Issues*, 1999, para 4.73.

⁷³ See GRAIN, *TRIPS versus biodiversity: Options for the 1999 review of Article 27.3(b) in the context of the CBD*, 1999.

⁷⁴ “The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.”

b) TRIPS

In broad terms the objectives of TRIPS⁷⁵ are:

- To create minimum standards of intellectual protection that all States wishing to be parties to the WTO trading system must recognise (Parts I and II).
- To ensure that states make available to rights holders institutional procedures to enforce their intellectual property rights (Part III).
- To provide a procedure for regulating disputes between states concerning their obligations under the agreement (Part V).

Article 7 of TRIPS refers to the objectives of the agreement in terms of the “promotion of technological innovation” and the “transfer and dissemination of technology”. These objectives are tied to the protection and enforcement of intellectual property. In any characterisation of the objectives of TRIPS a WTO panel would take as its point of departure the need to provide adequate and effective protection of intellectual property rights.

2.1.2.2. Treaty interpretation

The following observations are relevant to the interpretation of TRIPS and the CBD:

- The CBD was opened for signature in 1992 and came into force in 1993. TRIPS was part of the Final Act of the Uruguay Round that was signed in 1994, and TRIPS came into force in 1995. Neither treaty specifies that it is subject to the other. Article 22 of the CBD does state that the CBD shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement. TRIPS was not in existence at the time the CBD came into force.
- Article 30 of the *Vienna Convention On The Law Of Treaties* deals with the interpretation of successive treaties relating to same subject-matter. It is doubtful that one could characterise the two treaties as dealing with the same subject-matter. Indeed, some of the strongest supporters of TRIPS assert that they do not. TRIPS deals with standards of intellectual property law. The CBD deals with control over biological diversity. If the two treaties could be regarded as relating to the same subject-matter as between parties to both, the rule is that the earlier treaty applies only to the extent that its provisions are compatible with those of the later treaty (See Article 30.4(a) and 30.3 of the *Vienna Convention*). It might also be argued that TRIPS is the more detailed treaty (making use of the principle that the specific is to override the general). TRIPS prescribes detailed standards of intellectual property protection, even dealing with such matters as the burden of proof in relation to infringement of process patents. TRIPS also incorporates, by reference, provisions from the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits. To the extent that the provisions of these treaties have a precise and settled meaning that meaning would also probably be incorporated into TRIPS. Article 1 of TRIPS makes it clear that its provisions have to be implemented in the legal systems of its members. The CBD requires its contracting parties to take measures to meet the goals of conservation, sustainable development and benefit-sharing in relation to the use of biological resources. The provisions of the CBD tend to create obligations of a general kind. Note also that Article 22 of the CBD seems to set quite a high threshold of damage or threat to biological diversity before its terms apply to other international conventions.

⁷⁵ Article 7 *Objectives*. “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”.

All this suggests that it will be very difficult for a state to invoke successfully the CBD in order to justify a breach of its obligations under TRIPS.

2.1.2.3. Legal interpretation of the interaction between CBD and TRIPS

a) Article 16 of the CBD

Article 16. Access to and Transfer of Technology

1. Each Contracting Party, recognising that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.
2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognise and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.
3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.
4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.
5. The Contracting Parties, recognising that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

The CBD and TRIPS do not refer to each other. Article 16(5) of the CBD recognises that intellectual property rights “may have an influence on the implementation” of the CBD. It obliges states to cooperate in order to ensure that intellectual property rights are “supportive of and do not run counter to” the objectives of the CBD. At the same time Article 16(2) states that the technology transfer process is to be consistent with “the adequate and effective protection of intellectual property rights”. This obligation itself needs to be consistent with paragraphs 16(3), (4) and (5).

The measures that states can enact under Article 16(3) in order to gain access to technology must comply with the principle of mutually agreed terms and be consistent with international law. TRIPS is part of international law. Similarly, the measures in Article 16(4) that relate to private sector facilitation of access to technology are made subject to the obligation concerning intellectual property in Article 16(2).

Essentially Article 16 of the CBD preserves the entitlements of intellectual property owners as they are defined in international law (such as TRIPS).

b) Interaction of subject matter

The scope of the application of TRIPS is defined in terms of the categories of intellectual property protection to be found in Part II of TRIPS. The categories dealt with there are as follows:

- Copyright and Related Rights
- Trademarks
- Geographical Indications
- Industrial Designs
- Patents
- Layout-Designs (Topographies) of Integrated Circuits
- Unfair Competition

There is a range of subject matter to which the CBD relates including the following:

- technology (defined to include biotechnology) that relates to conservation and sustainable use;
- biological resources (defined to include genetic resources, organisms, or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity; genetic resources are defined to include genetic material which in turn reduces to functional units of heredity);
- habitats;
- ecosystems;
- information from all publicly available sources that relates to conservation and sustainable use;
- indigenous and traditional knowledge;
- indigenous and traditional technologies.

Clearly, the interaction between the rights referred to in TRIPS and the subject matter of the CBD is considerable.

Software which relates to conservation, for example, or information that relates to sustainable use may be the subject of copyright protection. This means that a price may be charged for its use. It should also be noted that much scientific information related to conservation and sustainable development is to be found in databases. In some jurisdictions databases may be protected under copyright principles, while in others databases may be protected by means of *sui generis* legislation⁷⁶. During the unsuccessful negotiations over the proposed WIPO Database Treaty some scientific groups voiced the concern that database protection would adversely impact on the exchange of scientific data⁷⁷. *Access to proprietary databases containing valuable biodiversity related information could become an important issue.*

Geographical indications may possibly be used to meet the goals of the CBD. The CBD itself recognises the existence of geographically defined areas that are regulated to achieve conservation objectives (see the definition of 'protected area' in Article 1). Such areas could also be geographical indications, if producers decided to link their collective production standards to conservation goals. Indigenous knowledge could be the subject of trade secret protection. Trade marks are important to the marketing of goods that are consistent with sustainable development. Trade marks are also relevant to the direct appropriation of biological resources, since smells may be registered as a trade mark.

⁷⁶ See, for example, Directive 96/9/EC Of The European Parliament And Of The Council of 11 March 1996 on the legal protection of databases. The US has introduced the Collections of Information Antipiracy Act into the House of Representatives.

⁷⁷ For example, it was argued that data base protection would hinder the free exchange of basic meteorological data amongst the scientific communities of countries.

c) Article 27 of TRIPS⁷⁸

The strongest overlap between IPRs and biodiversity-related matters is generally recognised by stakeholders and actors as occurring in section 5 of TRIPS which deals with patents.

Article 27 requires Members to recognise both product and patent processes without any discrimination as to the field of technology. The reference to technology would include biotechnology. In biotechnology product patents have been granted on, amongst other things, DNA sequences, genes (including human genes), the products of genes, micro-organisms, transgenic animals and plants. Process patents have been granted on, for example, fundamental techniques in recombinant DNA technology.

Article 27.2

Article 27.2 allows members to exclude from patentability inventions so as to protect ordre public or morality. This exclusion is linked to the prevention of the commercial exploitation of the invention. *Ordre public* and morality are given an inclusive extension. They include the protection of human, animal or plant life or health and the avoidance of serious prejudice to the environment. The exclusion from patentability cannot be made simply because the exploitation of the invention is prohibited by law.

On the face of it Article 27.2 confers a considerable discretion on states to regulate the grant of patents. Fundamental concepts within Article 27 such as the concepts of invention, ordre public and morality are not defined. There is a variety of academic and other opinion on what it is permissible for a state to do under the discretion granted to it in Article 27.2⁷⁹. It has been argued, for example, that the lack of a definition of invention means that states can take a flexible approach to the patenting of substances in nature⁸⁰. In making use of 27.2 Members will also need to bear in mind their general obligation under Article 8 of TRIPS to adopt measures that are "consistent with the provisions of this Agreement".

A WTO panel in looking at this Article may try and ascertain whether there is some common state practice when it comes to provisions that deal with excludability from patentability. If, for example, it concluded that it was accepted by many states that exceptions to patent law were to be construed

⁷⁸ Article 27 Patentable Subject Matter:

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.* Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Member may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is *not made merely because the exploitation is prohibited by their law*.

Members may also exclude from patentability:

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

* For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

⁷⁹ For a discussion see D. Leskien and M. Flitner, 'Intellectual Property Rights and Plant Genetic Resources: Options for a *Sui generis* System', Issues In Genetic Resources, IPGRI, 1997, chapter 1.

⁸⁰ Carlos Correa, 'Patent Rights' in Carlos Correa and Abdulqawi Yusuf, *Intellectual Property and International Trade: The TRIPs Agreement*, Kluwer Law International, London, 1998, 189, 198

narrowly then this might set a limit on the use that states could make of Article 27.2. It is, for example, a fundamental axiom of EC and US patent law that exceptions to patent law are to be narrowly construed⁸¹. This axiom has continued to be followed since TRIPS has come into operation. It might be reasoned by a WTO dispute panel that this axiom constitutes a customary interpretative principle in relation to Article 27. It might also be noted that most developing states do not have a significant body of indigenous patent jurisprudence and so to the extent that a WTO panel can find customary interpretative rules they are likely to find them in the patent jurisprudence of developed states or developing states which are following western patent jurisprudence. Putting the point another way the patent law of the US and the EU as well as the practice of those states in relation to TRIPS is likely to function as an interpretative resource for a WTO panel in a way that the patent law and practice of Rwanda is not.

One implication of this line of argument is that developing states should be wary of adopting model laws that are drawn from the major patent jurisdictions. The more diverse the practice of states under Article 27 the more likely it is that the Article will be read permissively by a WTO panel.

Article 27.3(a)

Article 27.3(a) gives Members a discretion as to the patentability of diagnostic, therapeutic and surgical methods for the treatment of humans or animals. While states can exclude methods of medical treatment from patentability the broad trend seems to be towards a narrowing of this exception. The use of patents in the area of medical treatment has attracted controversy. For example, the grant of a patent to a surgeon over a method of surgical incision and subsequent patent infringement proceedings in 1993 lead to public condemnation of this use of patents by the American Medical Association⁸². Subsequently the US Patent Act was amended to exempt from infringement medical practitioners who used patented surgical techniques (see 35 USC 287(c)).

Although beyond the study TOR, the link between patents and medical treatment is part of a much bigger and growing issue about the impact of TRIPS on health care, especially the access to essential drugs. One of the key concerns is whether TRIPS will allow members to safeguard their public good objectives in the health care area⁸³. *Fears from this area, and experience of how it is dealt with, undoubtedly affect the way actors concerned with biodiversity view possible impacts.*

Article 27.3(b)

WTO Members also have a discretion as to the patentability of plants, animals, biological processes for the production of plants or animals and plant varieties. If they choose not to grant patent protection for plant varieties they are obliged to provide protection by means of an effective *sui generis* system.

Article 27.3(b) makes mandatory patent protection for micro-organisms and non-biological and microbiological processes for the production of plants and animals. There has been a great deal of discussion as to the meaning of *sui generis* in Article 27.3(b). An analysis based on the ordinary meaning of the term would suggest that a state was free to implement a system of its own design for the protection of plant varieties or alternatively that it could choose to implement the UPOV system. Such an interpretative approach would be consistent with the approach of the WTO panels in the

⁸¹ PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors [1995] EPOR, 357, 372; LUBRIZOL/Hybrid plants [1990] EPOR 173, 177; *Diamond v Chakrabarty* 206 USPQ 193, 200 (1980), 196-197.

⁸² P.W. Grubb, *Patents For Chemicals, Pharmaceuticals and Biotechnology*, OUP, 1999, 219.

⁸³ See Z. Mirza, WTO, 'Pharmaceuticals and Health: Impacts and Strategies', International Roundtable on Responses to Globalization: Rethinking equity in health, Geneva, July 12-14, 1999; *Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement*, Health Economics and Drugs, DAP Series No. 7., World Health Organisation, 2nd edn.1999.

India-Patent Protection For Pharmaceutical And Agricultural Chemical Products complaint proceedings. There the panels following the rules of interpretation laid down in Article 31 of the *Vienna Convention* began by looking at the ordinary meaning of the terms in question.

If a state chose to implement its obligation under 27.3(b) by means of a *sui generis* system that system would have to be effective. The term effective would be read in the light of the object and purposes of TRIPS, which according to Report of the Appellate Body in India-Patent Protection For Pharmaceutical And Agricultural Chemical Products complaint proceedings includes “the need to promote effective and adequate protection of intellectual property rights”⁸⁴.

In short, the meaning of effective sui generis system is to be determined in part by the need to provide effective intellectual property protection. In order to make sense of this circularity a WTO panel may well look at the practice of states in relation to 27.3(b). If, for example, many states were in fact adopting UPOV 91 for the purposes of 27.3(b) it might be concluded that that set of standards constituted effective protection. This would not mean, however, that a state would be obliged to join UPOV, but rather that it would have to meet UPOV standards. Obviously states have a sovereign discretion as to how to implement their obligation to provide ‘effective’ protection in this context (recognised in Article 1.1 of TRIPS), but the judgement as to whether they have met the standard of effectiveness that is required under TRIPS is a matter for a WTO dispute panel (see Article 1 and Appendix 1 of the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes). Clearly, if there is no consistent state practice in relation to 27.3(b) it would make it more difficult for a WTO dispute panel to decide what constituted an effective set of standards.

Though it is believed that some developed countries (such as the US) may seek to have Article 27.3 (b) removed entirely from TRIPS so that there will be virtually no restrictions at all on the patenting of life-forms, for the time being, the US and other industrialised countries are content to emphasise implementation of the current provisions including the *sui generis* option and to block any re-opening of negotiations on the actual text of the agreement.

There is no doubt that better co-ordinated and informed intervention on the part of developing countries is a major factor in this more cautious developed country stance, as developing countries are becoming less reactive and more proactive in IPR-related debates at the WTO including discussions on the CBD relationship.

d) Impact on TRIPS provisions of national standard setting

The practice of states in the setting of national intellectual property standards may affect the meaning of provisions of TRIPS. TRIPS is an unusual trade instrument in that it is the only case of ‘positive’ linkage of regulatory standards to the GATT - where states are required to enforce specified minimum standards⁸⁵. All other linkages in the history of the GATT have been ‘negative’ - states have been required to strike out national standards (eg, lowering of tariff barriers). In many cases the positive standards that TRIPS sets are left undefined. At what level, for example, is a state to set the standards of inventiveness or utility that are referred to in Article 27.1? Clearly these could be set in such a way so as to defeat patenting in biotechnology altogether, making the obligations in 27.3(b) a dead letter. In order to avoid this self-defeating result a WTO panel would have to look towards

⁸⁴ WT/DS50/AB/R, 57

⁸⁵ See Frederick M. Abbott, ‘WTO Dispute Settlement and the Agreement on Trade-Related Aspects of Intellectual Property Rights’ in Ernst-Ulrich Petersman, *International Trade Law and the GATT/WTO Dispute Settlement System*, Kluwer Law International, 1997, 415.

setting the positive standards of TRIPS at a level that was consistent with the purpose of TRIPS. When an issue arises as to the meaning of a provision of TRIPS, such as in the case of 27.3(b), a WTO panel may well look to see whether national standards are gravitating towards some common standard or practice in order to cast light on the positive standard that TRIPS requires. To some extent this puts the major patent jurisdictions (the US, the EU and Japan) in the driver's seat since they are in the position of greatest influence when it comes to the international harmonisation of patent law.

In the case of Article 27.3(b) it is significant that the major intellectual property jurisdictions are moving towards a system of multiple protection for biological resources. Recently the US Court of Appeal in *Pioneer Hi-Bred International, Inc. v J.E.M. Agriculture Supply* (decided January 19, 2000) concluded that patents over plants and seeds for new varieties of hybrid and inbred corn were patentable subject matter under 35 USC 101. The argument that the Plant Protection Act and the Plant Variety Protection Act were to be treated as the exclusive forms of protection for plants was rejected. Although the European Patent Convention contains an express prohibition on the patenting of plant varieties in Article 53(b) it is likely that European patent law will evolve in a way that allows this prohibition to be overcome by means of the drafting of patent claims. For example, in the recent *Novartis* decision of the Enlarged Board of Appeal on 20 December 1999 it was concluded that it was "in agreement with the rules of logic that a patent shall not be granted for a single plant variety but can be granted if varieties may fall within the scope of its claims" (3.10). Article 4(2) of the Biotechnology Directive will also facilitate a drafting strategy to overcome the prohibition on the patenting of plant varieties. Internationally members of UPOV signalled the move towards dual protection when the prohibition on the simultaneous use of plant breeders' rights and patents was abandoned in UPOV 1991.

Whether the attempt in Article 12.3 of the Biotechnology Directive in the EU to balance the interests of plant breeders and patent holders by means of compulsory licences will achieve its intended aim is open to question. The grant of compulsory licences is a matter dealt with in Article 31 of TRIPS. The provision requires, amongst other things, that authorisation be considered on its individual merits, that efforts have been made to obtain a licence on reasonable commercial terms and that the right holder is paid adequate remuneration. Plant breeders faced by complex patent licensing webs over plant material may not be able to make much practical use of compulsory licence provisions that meet the requirements of TRIPS.

2.1.2.4. Possible legal issues raised by the interaction

The interaction between the CBD and TRIPS raises three key questions:

- (1) Is there a conflict between the provisions of the two agreements?
- (2) Does the use of intellectual property rights in biotechnology and genetic material undermine the CBD objectives of conservation, sustainable use, indigenous knowledge and benefit sharing?
- (3) If the answer to (2) is yes does TRIPS permit states to adjust their national intellectual property laws in ways that prevent the uses of intellectual property rights that are inconsistent with CBD objectives?

We examine each of these in turn as a way to clarify the issues.

a) Legal conflicts between the two agreements

It is hard to sustain the claim that there is a direct legal conflict between the two agreements. The CBD is a framework agreement that imposes obligations of the most general kind. On the face of it there is nothing in the provisions of either agreement that would prevent a state from fulfilling its obligations under both. The CBD, for example, does not prohibit patents on genetic material. Similarly the declaration of state sovereignty over resources in Article 3 of the CBD does not conflict with TRIPS. Article 3 recognises the sovereign rights of states “to exploit their own resources”. Intellectual property rights are one means by which such resources may be exploited. The CBD itself obliges members to develop economic incentive measures for the conservation and sustainable use of biological diversity (see Article 11). Intellectual property rights clearly qualify as such measures.

b) Do IPRs undermine CBD objectives?

Answering the second question is much harder because it requires empirical data about the actual use of intellectual property rights and the effects of that use on conservation, sustainable use, indigenous knowledge and benefit sharing. At best our knowledge of the long run effects of intellectual property rights is incomplete. The discussion below takes each one of the three CBD goals and draws attention to those intellectual property rights that are likely to impact on that goal.

Conservation

The CBD places a heavy emphasis on *in situ* conservation (see the Preamble which describes *in situ* conservation as the *fundamental* requirement for conservation and see also Article 8). The definition of *in situ* conservation makes it clear that the goal of conservation is to preserve the ecosystems and natural habitats of biological organisms. Generally speaking, intellectual property rights serve dynamic efficiency goals - the development of new technological knowledge - and so could only be expected to serve indirectly at best the goal of the conservation of biological diversity. The two forms of intellectual property most relevant to conservation are patents and plant variety rights.

- *Plant Variety Rights*

Plant variety regimes deal with a sub-set of biodiversity, plant genetic resources, and explicitly allow for the registration of a plant variety that has been discovered. UPOV defines a breeder to mean the person who bred, or discovered and developed, a variety (see Article 1 of UPOV Act 1991). Such a variety must be distinct, stable, sufficiently uniform and novel. A property right in a plant variety that exists naturally may provide an incentive for the conservation of that plant. Whether or not in practice such a property right will actually function in this way is dependent upon a number of factors, including whether a person holding such a property right has access to a distributional and marketing infrastructure.

- *Patents*

Patents are said not to be available for discoveries. However, there are numerous qualifications to this proposition. The line between discovery and invention is thin. Patent law in biotechnology in the major jurisdictions recognises that a patent may be granted on a gene sequence that is derived from a naturally occurring gene sequence, if the sequence in question has been purified and isolated. Under US law (35 USC 100(a)) invention is said to mean invention or discovery. The purpose of this definition is to make it clear that an invention may incorporate a discovery and still remain eligible for patent protection.

One consequence of the blurring of the distinction between invention and discovery in the context of patent law might be that patent rights provide a heightened incentive for the conservation of existing genetic resources. Plants are a crucial source of medical products⁸⁶.

Whether or not the patent system will have a positive effect on the conservation of *in situ* existing biological diversity, both domesticated and non-domesticated agriculture, remains a matter of conjecture. For example, the search by companies for patentable biological resources in biodiverse rich areas does not necessarily promote conservation goals. Recently it was reported that the bark of the African Bobgunnia madagascarensis contained a chemical that could treat thrush, athlete's foot and fungal infections of the eye. It was also reported that six large trees were destroyed in the process of extracting 50 grammes of the naturally occurring fungicide for the purpose of medical trials (Guardian, February 21, 2000, 8). The possibility of intellectual property rights in genetic resources may, in other words, trigger an over harvesting of existing biological resources.

The incentive to conserve plants like the African Bobgunnia madagascarensis may not extend to *in situ* conservation so far as companies are concerned. Essentially companies will want to ensure the reliability of supply of medicinally valuable plant genetic resources. They may, at least in some cases, prefer to establish their own *ex situ* sources of supply rather than trust to supply from *in situ* sources in developing countries that are politically and socially unstable. The company Eli Lilly for instance established supplies of the plant *Catharanthus roseus* in Texas because supplies from Madagascar were subject to interruptions. The plant is important in the development of anti-cancer drugs.

Patents may offer some incentive for the conservation of plant genetic resources, but this incentive does not translate into the conservation of *entire* ecosystems and natural habitats. Such conservation will have to be provided by governments as a public good. In any case the conservation effects of the patent property rights system are largely arbitrary. These effects are driven by the market judgements of the largest users of the patent system, the life sciences companies. If, for example, they conclude that combinatorial chemistry offers more likelihood of success of finding the next blockbuster drug than the screening of natural products the value of biodiversity for these companies falls to zero⁸⁷. Intellectual property rights only create the opportunity for a market value to be put on genetic resources. They do not automatically create that value. Moreover, the valuation of genetic resources has complex public and non-use dimensions that the use of intellectual property rights does not address⁸⁸.

In short, neither the plant variety rights or patent regime can be expected to make a significant contribution to in situ conservation. Conservation is fundamentally about protecting habitats and IPRs make no real contribution to this.

Sustainable use (Article 10 of the CBD⁸⁹)

⁸⁶ See Balick, *Medicinal Resources of the Tropical Forests*, Columbia University Press, 1996.

⁸⁷ On this point see D. Goldstein, 'A critique of the critics', *Biotechnology and Development Monitor*, September 1994, 20.

⁸⁸ For a discussion see W. Lesser, *Sustainable Use of Genetic Resources under the Convention on Biological Diversity*, CAB International, 1998, Ch.4.

⁸⁹ Article 10. Sustainable Use of Components of Biological Diversity

Each Contracting Party shall, as far as possible and as appropriate:

- (a) Integrate consideration of the conservation and sustainable use of biological resources into national decision-making;
- (b) Adopt measures relating to the use of biological resources to avoid or minimise adverse impacts on biological diversity;
- (c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;

The second goal of the CBD is to encourage the sustainable use of biological diversity. Sustainable use is defined to mean the use of biological diversity in “a way and at a rate that does not lead to the long-term decline of biological diversity” (Article 2). Biological diversity refers to the “variability among living organisms from all sources” (Article 2). Article 10 imposes some general obligations concerning the sustainable use of biological diversity. Amongst other things, it requires states to integrate consideration of sustainable use into national decision-making (Article 10(a)), adopt measures that avoid or minimise adverse impacts on biological diversity (Article 10(b)) and protect and encourage customary use of biological resources that aid sustainable use (Article 10(c)). The language of Article 10 of the CBD is highly general requiring only a ‘consideration’ of sustainable development and a minimisation of adverse impacts on biological resources.

TRIPS does not mention sustainable use. But sustainable development is not irrelevant to members of TRIPS. TRIPS becomes binding on states by virtue of their membership of the WTO (see Article II(2) of the WTO Agreement). The preamble to the WTO Agreement does recognise the principle of sustainable development. Members of the WTO in carrying out their rights and obligations under the various WTO agreements, including TRIPS, need to be cognisant of the broader purposes that membership of the WTO brings with it.

- *Technology transfer*

The transfer of technology is important in enabling sustainable development. Both TRIPS (Article 7) and the CBD seek to foster the transfer of technology. Article 7 of TRIPS refers to the ‘transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge’. Importantly Article 40.1 of TRIPS recognises that the licensing or other use of intellectual property rights ‘may impede the transfer and dissemination of technology’⁹⁰. Article 1, which deals with the objectives of the CBD, also recognises, that the ‘transfer of relevant technologies’ is one means by which those objectives are to be pursued. Article 16 of the CBD implicitly recognises the fact that most developing countries are in the position of being technology importers. Article 16(2), for instance, requires that technology transfer to developing countries take place ‘under fair and most favourable terms’.

There is a widespread perception amongst many involved in this area that the neither the CBD or TRIPS have really fulfilled the aim of technology transfer to developing countries. The role of intellectual property in the transfer of technology is beyond the scope of this report, but it is worth reporting the conclusion of one recent survey of the limited empirical work on this issue:

“[I]t would seem that the introduction of (stronger) patent protection in developing countries will entail significant costs: increased prices for consumers who cannot afford to pay these prices, loss of jobs and other economic benefits from local manufacture of pirated goods. These costs may not be compensated by technology transfer or investments by foreign companies. Surely empirical research does not indicate that compensation of this nature (the advancement of indigenous technological and innovative activities in developing countries) can be expected”⁹⁰.

(d) Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced; and

(e) Encourage cooperation between its governmental authorities and its private sector in developing methods for sustainable use of biological resources.

⁹⁰ See Sigrid Sterckx (ed), *Bioethnology and Morality*, Dartmouth, 1999, 96-97.

The impact of TRIPs on technology transfer goals of the CBD and indeed the impact of globalised intellectual property rights on the transfer and dissemination of technology that is a goal of TRIPs itself remains largely a matter of conjecture. Intellectual property systems for much of their history have been badly enforced, allowing therefore for considerable leakage of proprietary knowledge. As a result of TRIPs intellectual property owners are in a stronger position to enforce their rights. However, through the criminalisation of intellectual property infringement states are bearing an increasing part of that enforcement cost. With better international enforcement of intellectual property rights one would predict that technology transfer will become dominated by two factors, namely the ability to pay and the strategic market objectives of transnational intellectual property owners.

Developing countries do not have much control over either factor. Relevant to this issue is the use of compulsory licences. Article 16 of the CBD addresses the issues of access and transfer of proprietary technology in only a general way. Certainly it falls well short of authorising the use of compulsory licences to deal with the problem of the refusal to licence. Article 31 of TRIPS does permit a member to make use of compulsory licences, but the scope of this provision is obviously a matter of interpretation⁹¹.

- *Agricultural research as a public good*

Nothing in the CBD itself prohibits the emergence of scientific knowledge as an internationally traded good. Moreover, Article 10(e) of the CBD expressly obliges members to “encourage cooperation between its governmental authorities and its private sector in developing methods for sustainable use of biological resources”.

Various provisions of the CBD make it clear that states will have to encourage research into the conservation and sustainable use of biological resources (for example Article 10(e)). This will involve both private and public research sectors. One problem for developing countries that are beginning to develop public sector research programmes related to sustainable use is that many of the tools of biotechnology research are subject to proprietary control by mainly western intellectual property owners. Some tools are so fundamental that almost all other biotechnological research depends on the use of that tool. For example, the Cohen/Boyer patent issued in 1980, which related to gene-splicing techniques, gave exclusive control over the bulk of all genetic engineering processes⁹².

The CGIAR system has been the most important provider of international agricultural research as an international public good to developing countries. The network of international agricultural research centres that make up system holds the major *ex situ* collections of plant genetic resources of the major agricultural crops in trust for humankind (see 1.1.6.2). The system is a major contributor to the goals of the CBD in agrobiodiversity. Support for the CGIAR system is entirely consistent with the CBD. Article 18(1) of the CBD requires members to “promote international technical and scientific co-operation in the field of conservation and sustainable use of biological diversity, where necessary, through appropriate international and national institutions.” Members of the CGIAR system are increasingly concerned about the impact of widespread patenting of biotech research tools and genomic information on research within the CGIAR system. Members of CGIAR sometimes need to make use of proprietary technologies to carry out their research programmes. A study concluded in 1998 by ISNAR showed that selectable markers, promoters and transformation systems were the

⁹¹ See M. Halewood, ‘Regulating Patent Holders: Local Working Requirements And Compulsory Licences At International Law’ 35 (1997) *Osgoode Hall Law Journal*, 243.

⁹² P.W. Grubb, *Patents For Chemicals, Pharmaceuticals and Biotechnology*, OUP, 1999, 233.

most heavily used types of proprietary technologies by CGIAR researchers⁹³. Despite their public good approach to research, some centres are likely, even if reluctantly, to be forced to see IPR over their work as a means to defend it. Indeed CIMMYT has recently announced it will use patents and has been challenged over this policy change by RAFI⁹⁴. They also face considerably increased transaction costs in doing research due to the increasing use of lawyers and IPRs.

The possible impact of intellectual property on international public sector research is a complex and uncertain matter. Intellectual property rights held by CGIAR members may, for example, form the basis of private/public sector research partnerships in areas that might otherwise remain unfunded. On this basis some members of the CGIAR system take the view that intellectual property rights should be pursued and used. Less optimistically, the use of intellectual property to control biotech research may compromise the capacity of the CGIAR system to fulfil its public goods mission. Scientific knowledge in general is becoming increasingly propertised. Most universities have intellectual property statutes that govern the ownership of intellectual property rights generated by their employees and most have a technology-licensing arm. A small number of universities such as the University of California System, Stanford University and Columbia University have become big royalty winners from technologies that they have protected with intellectual property⁹⁵. Scientific research in developed countries is increasingly done by transnational networks made up of public and private sector partners. For public sector instrumentalities, intellectual property rights function as a means to integrate themselves into these networks. In biotechnology and agriculture it is likely that much research will end up as an international rather than public good and that it will be distributed according to complex licensing structures. It will be more or less impossible for the CGIAR system to remain outside of this paradigm of propertised science.

- *Cultural practices*

Article 10(c) of the CBD requires members to “protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements”. In the CBD, the obligation to protect traditional cultural practices is conditional upon those practices serving the goal of conservation and sustainable use. The words ‘traditional cultural practices’ are not confined to any group. They could apply to the customary practices of any distinct group whether these are the traditional practices of indigenous groups in the Amazon basin or the practices of traditional farming communities in a western state.

There are a number of traditional practices of farmers in all countries that are relevant to the goals of conservation and sustainable use: the maintenance and continued development of traditional varieties, the saving and exchange of seed. Small farmers in many countries save seed from one harvest to the next to have a stock of seed to plant for the next season, and to select for better crops or sought-after characteristics. The exchange of seed is a common practice in traditional farming communities.

Parts of intellectual property law may cut across some customary uses of biological resources. This will depend on the way in which states exercise the various options given to them under international treaties, as well as the way that national courts interpret their existing laws of intellectual property.

⁹³ J. Cohen, C. Falconis and J. Komen, ‘Perspectives from International Agricultural Research Centres’ in U. Lele et al, Intellectual Property Rights in Agriculture, World Bank, Washington DC, 2000.

⁹⁴ Rafi, <http://www.rafi.org>, “The Spill out from CIMMYT’s Revised Patent Policy, 12 April 2000

⁹⁵ See D. Parker et al, ‘Offices of Technology Transfer: Privatising University Innovations for Agriculture’, Choices, First Quarter, 1998, 19.

The UPOV Convention in Article 15(2), for instance, grants members the option of restricting a breeder's right "to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings". Article 15(2) makes no reference to farmers being permitted to exchange seeds for propagation. Importantly, Article 15(1) also creates some compulsory exceptions that relate to private use, experimental use and acts done for the purpose of breeding other varieties. These compulsory exceptions would give a court minded to do so considerable scope to achieve a balance between customary practices relating to biological resources and the rights of plant breeders.

The patent system in its present state is likely to prove less amenable to adjustment when it comes to the issue of customary uses of biological resources. For example, a patent claim over a gene that had been inserted into a plant variety would give the patentee strong control over all commercial uses of that gene. This control of the patentee is further strengthened by the fact that exceptions to the patentee's rights are, as a general proposition, fewer than for other types of intellectual property rights, as well as being more narrowly construed. Patent law does, for example, recognise a restriction on the patentee's rights for purposes of experimentation, but that restriction is for the most part narrowly construed. In the US the experimental defence to an infringement action is a creation of the courts. It "has been frequently raised but rarely sustained"⁹⁶. German patent law also keeps the experimental exemption within narrow bounds⁹⁷. If the experimental use leads to a useful product or process, its exploitation may depend on permission of the patent holder – which in itself may discourage others from investing in experimental work since use of its results are subject to a veto.

Protection of Indigenous Knowledge⁹⁸

Article 8(j) of the CBD is one of the articles that serves the purpose of in-situ conservation. It imposes on states, subject to their national legislation, a preservationist duty with respect to the knowledge, innovations and practices of indigenous and local communities insofar as that knowledge, innovation and practice serves the goals of conservation and sustainable use of biodiversity. It also requires states to diffuse that knowledge, innovation and practice with the cooperation of the holders of that knowledge. Finally, the article requires states to encourage the sharing of any benefits that arise from such diffusion.

Article 8(j) deals with the protection of indigenous knowledge. It thus contemplates some form of protection in intangibles. Access to biological resources is a separate matter that is being dealt with by many states under national access laws. In the case of plant genetic resources for food and agriculture, the IU, once completed, will regulate access and benefit sharing. The broad thrust of these national laws is to provide a procedure that an applicant has to go through to gain access to a state's biological resources. Progressively, the informal norms that have governed the collection and use of biological resources for most of human history are slowly being replaced by formal national regimes that impose a variety of conditions upon potential users. These conditions can include

⁹⁶ R. Eisenberg, 'Patents and the progress of science: exclusive rights and experimental use', 56 (1989) *University of Chicago Law Review*, 1017.

⁹⁷ See Case No.XZR 99/92, Federal Supreme Court, July 11, 1995, reported in English in 28 (1997) IIC, 103. See also J. Pagenberg, 'Comment' same volume 111-113.

⁹⁸ *Article 8. In-situ Conservation.* Each Contracting Party shall, as far as possible and as appropriate:

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices;

(k) Develop or maintain necessary legislation and/or other regulatory provisions for the protection of threatened species and populations;

conditions relating to the consent of indigenous or local groups, quantity restrictions, compensation obligations, restrictions on the transfer of the material and obligations not to seek intellectual property rights over the material or not to seek them without permission.

Article 8(j) is open-ended about the means that states might employ to meet their obligations of preservation and diffusion. It does not, for instance, require the development of legislation to this end (compare Article 8(k)). States, then, can choose from a range of policy options to meet their obligations under Article 8(k). If states choose to use intellectual property rights to meet their obligations under Article 8(k) they have the following options:

1. They may choose to allow their existing intellectual property regimes to apply to indigenous knowledge. Such an option might be consistent with both the CBD and TRIPS. The obligations in Article 8(j) of the CBD are made subject to national legislation. The reason for this was to preserve national legislation that related to indigenous knowledge before the commencement of the CBD⁹⁹. The clause presumably picks up national intellectual property legislation since that legislation would clearly have been relevant to issue of the protection of indigenous knowledge. As a general rule indigenous groups will do best from existing intellectual property regimes where they have kept their knowledge secret and/or where they can point to an individual holder of that knowledge.

Some people take the view that existing intellectual property regimes do not adequately protect indigenous knowledge. This may not be a problem so far as the CBD is concerned. The CBD justifies the obligations in Article 8(j) in an instrumental way - indigenous and local knowledge is to be protected to the extent that it serves the goals of conservation and sustainable use. The fact, therefore, that some indigenous knowledge falls outside of existing intellectual property rights regimes does not mean that the operation of those regimes is inconsistent with the CBD. The absence of property rights in indigenous knowledge may in fact aid its diffusion. The diffusion of information related to conservation and sustainable development is one of the goals of the CBD. However, free-riding on indigenous knowledge will lead to public criticism, as well as allowing NGO groups to foster public discord over the operation of the existing intellectual property system.

2. States may choose to adapt their existing intellectual property laws to make such laws more usable by indigenous and local groups.
3. States may choose to enact a *sui generis* model of intellectual property protection for indigenous and local knowledge. Nothing in TRIPS prevents the development of new forms of *sui generis* protection. The provisions of such national *sui generis* models would have to be consistent with TRIPS. A provision, for example, which prohibited biotechnological inventions would not be consistent with the requirement in Article 27(1) that "patents shall be available for any inventions" if, as seems likely, the meaning of invention includes biotechnological processes and products. A number of states are going down the path of creating such *sui generis* models. The development of model *sui generis* indigenous intellectual property legislation is currently the subject of work by the Crucible Group.

There are economic arguments that are worth considering in relation to the creation of a *sui generis* model of intellectual property protection for indigenous knowledge. Present intellectual property

⁹⁹ M. Blakeney. 'The International Framework of Access to Plant Genetic Resources' in M. Blakeney (ed) *Intellectual Property Aspects of Ethnobiology*, Sweet & Maxwell, 1999, 9.

regimes do not fit particularly well with indigenous innovation systems. The resulting uncertainty for indigenous groups may make them reluctant to disclose their knowledge and enter into partnerships with commercial entities interested in the exploitation of their knowledge. The creation of well-defined property rights in indigenous knowledge may serve to facilitate contracting between indigenous groups and industry. Any national legislation for the protection of indigenous knowledge would, however, by virtue of the principle of territoriality only operate within the state that passed the legislation. To secure international protection for indigenous knowledge based on minimum standards and the principle of national treatment an international treaty would have to be negotiated. The prospects of this happening could not be described as immediate or even likely. There may, however, be a contractual solution to this problem in the form of a Global Bio-Collecting Society. We discuss this option in section D.

Benefit Sharing¹⁰⁰

The fair and equitable sharing of benefits is the third major goal of the CBD. It includes a non-monetary dimension. Article 1 says that benefits include appropriate access to genetic resources, transfer of technology and appropriate funding. The obligation to share in the benefits (both commercial and non-commercial) flowing from the use of genetic resources is to be found in Article 15(7). Article 19(2) repeats the principle of benefit-sharing in relation to biotechnologies based upon genetic resources. Article 16 expands on the meaning of access to and transfer of technology.

The CBD is not prescriptive about the way in which benefit sharing is to take place, except to say that it must be mutually agreed. It might also be argued that the CBD entrenches a desert-based approach to the distribution of benefits rather than a needs-based one. Benefits are to go to those contracting parties that provided the genetic resources that have generated the benefits in question. This desert-based principle is somewhat problematic in this context.

The distribution of wild genetic resources amongst the countries of the world owes more to the accidents of geography and climate and of agricultural genetic resources to exchange between farming communities and cultures throughout the world over millennia of agriculture, than it does to meritorious design on the part of those countries that hold valuable genetic resources. Nor will it necessarily be the case that developing countries will always benefit from this desert-based principle. Moreover, countries that are rich in wild genetic resources need not be rich in agricultural genetic resources. Some wild biodiversity rich countries, such as Brazil, depend almost totally upon imported biodiversity for their food and agricultural crops. This distinction has implications for the types of property and intellectual property regimes involved. In practice, access and benefit-sharing for wild resources under the CBD is addressed through bilateral mechanisms. Multilateral mechanisms may better express the interdependence that characterises agriculture, as is recognised in the negotiations for the revision of the IU.

¹⁰⁰ Article 15. Access to Genetic Resources...

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 19. Handling of Biotechnology and Distribution of its Benefits...

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

Benefit-sharing obligations under the CBD are to be achieved by parties using legislative, administrative and policy measures. The basic issue that arises is whether TRIPS-based national intellectual property regimes aid or interfere with the measures that members of the CBD and TRIPS are taking to achieve the goal of benefit-sharing. This question can only be answered on a case by case basis. The Conference of the Parties to the CBD have called for “case studies on the relationships between IPRs and CBD objectives, including technology transfer and benefit-sharing with indigenous and local communities”¹⁰¹.

If empirical work reveals that TRIPS based national intellectual property regimes are undermining benefit sharing the question will become whether TRIPS allows sufficient scope for the adjustment of intellectual property regimes in a way that is consistent with the goal of benefit sharing. The interpretation of TRIPS by WTO Panels, especially of Articles 8, 27.(2) and (3), 30 and 40, will prove absolutely crucial to the normative co-existence of TRIPS and the CBD.

It may also be that intellectual property rights can be adjusted in ways that positively aid the goal of benefit sharing as opposed to simply not interfering in benefit-sharing. For example, it has been suggested that it be mandatory that patent applications be accompanied by certificates of origin that disclose the source of the biological resource in question¹⁰². Such certificates could also be used to check whether other principles of the CBD, such as consent of the donor, had been met. Some of the developing country actors we consulted saw considerable merit in the use of certificates of origin. In order for such a proposal to be fully effective it would have to become a topic of patent law harmonisation amongst the three major patent law jurisdictions, the US, the EU and Japan. This issue was discussed recently at the meeting of WIPO member states in relation to the draft Patent Law Treaty. Member states agreed to continue discussing the issue in the WIPO context. The Biotechnology Directive does in its Preamble (see Recital 27) refer to the desirability of providing information as to origin, but nothing of consequence flows from the failure to provide such information. Some developing country interviewees we spoke to see this as an example of symbolic and ineffective regulation. Support by developed countries for certificates of origin is being read by some developing countries as an indicator of the level of good faith that exists on the issue of benefit-sharing.

- *Biopiracy and Intellectual Property*

Biopiracy is not a term of legal art. It is largely used by activists as a rhetorical tool to condemn the conduct of corporations that seek to obtain some form of intellectual property protection over biological resources that are seen as ‘belonging’ to developing countries or indigenous or local groups. Whether or not a given biological resource is or is not the subject of legal ownership is not something that is finally determined by the CBD. As the CBD makes clear, this is a matter for states to determine using their sovereign authority over natural resources. A corporation using intellectual property rights to gain control over a biological resource may not breach any legal obligations.

At a practical level, however, it would be imprudent for policy makers to ignore the complaints of biopiracy. The US during the 1970s and 1980s when it was campaigning to create TRIPS made extensive use of the term ‘piracy’ to characterise the conduct of developing countries in respect of US intellectual property. It is far from clear whether all the developing countries that were accused of piracy by the US were in fact in breach of treaty obligations dealing with intellectual property. Some developing countries were in fact not members of such treaties. If nothing is done to address the complaints of biopiracy there will be an increasingly strong perception that WTO regimes such as

¹⁰¹ Graham Dutfield, *Intellectual Property Rights, Trade and Biodiversity*. Earthscan, 2000.

¹⁰² Graham Dutfield, *Intellectual Property Rights, Trade and Biodiversity*. Earthscan, 2000

TRIPS are designed to solve free-riding problems that matter to the corporations of key developed countries and no others. The present crisis of legitimacy that has beset the WTO regime will continue to deepen. Alliances between developing countries and NGO actors from social movements that transcend North South boundaries will see citizen activism directed at supra-national regulatory institutions such as the IMF and the WTO rise to new levels. Developing countries will begin to think more strategically about self-help remedies. So, for example, one interviewee pointed out that some players in developing countries were thinking about some sort of systematic listing of corporations that engage in biopiracy. For the time being this is a weak enforcement strategy. However, it may become stronger if developing countries find ways to support collectively the listing option and to bring such incidents to the attention of mass publics in developed countries.

2.1.3. (Legal) issues raised by the International Undertaking (IU)

During the 1970s developing countries, which had pushed for the recognition of the principle of common heritage of mankind in relation to technological knowledge, began to question fairness of the application of the principle to plant genetic resources. This issue was discussed by states in the Food and Agriculture Organisation and eventually the discussions led to the adoption of the International Undertaking On Plant Genetic Resources in 1983 (IU) as a non-binding international agreement to promote the conservation and sustainable utilisation of plant genetic resources for food and agriculture¹⁰³ (see 1.1.5). In its initial conception the IU was “based on the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction” (see Article 1). The obligations that the IU created were not tied to a mechanism of legal enforcement. States merely had to report on a yearly basis to the Director-General of the FAO as to the steps they had taken to implement the objectives of the IU (Article 11).

Common heritage is an ambiguous concept¹⁰⁴. It may mean that a resource is not the subject of ownership (ie, in the commons) and therefore it is open to anyone to appropriate, or it may mean that the resource is the subject of common ownership and cannot be appropriated without the consent of all. Essentially, the evolution of the IU suggests that it is the former rather than latter conception of common heritage that the international community is progressively moving towards.

In resolution 4/89 of the 25th Session of the FAO Conference in Rome 1989 the Conference qualified the principle of common heritage in the IU in the following ways:

- Plant Breeders' Rights were declared not to be incompatible with the IU;
- The discretion of states to impose restrictions on the free exchange of materials that were consistent with their national and international obligations was recognised;
- It was agreed that free access did not mean free of charge
- It was agreed that the IU operated on the basis of reciprocity ie, the principle of common heritage no longer applied to all mankind but only to those in states that were part of IU.

The operation of the principle was further qualified in Resolution 3/91 where it was recognised that nations had sovereign rights over their plant genetic resources and that breeders' lines and farmers' breeding material should only be available at the discretion of their developers during the period of development. Clearly, the scope of operation of the principle of the common heritage of mankind has been considerably reduced in the context of the IU.

¹⁰³ Resolution 8/83 adopted by the FAO Conference at its 22nd Session in 1983.

¹⁰⁴ For a discussion of it see Peter Drahos, *A Philosophy of Intellectual Property*, Dartmouth, 1996, ch. 3.

Since 1994, the IU has been under renegotiation, in harmony with the CBD, to provide a system of multilateral access and benefit-sharing that takes into account *“the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions”*. The draft text as it presently stands is no longer driven by the principle of common heritage. Draft Article 1 changes the objectives of the IU. Article 1 of the 1983 IU stated that the objective of the IU was to make plant genetic resources available for plant breeding and scientific purposes. Draft Article 1 currently refers to the objectives of the IU as conservation, sustainable use and benefit sharing in harmony with the CBD for the purpose of sustainable agriculture and food security. It is also clear from the present negotiations that the broad multilateral co-operation that was mandated by IU 1983 for “plant genetic resources of economic and/or social interest” will eventually be replaced by a system of multilateral co-operation in relation to a restricted number of crops, which are important for food security, and for which countries are interdependent. By implication those crops that are not expressly listed as being part of the multilateral system will become the subject of bilateral dealing under the terms of the CBD. Even those crops that are part of the multilateral system access may be further restricted according to the purpose for which access is sought.

2.1.3.1. The ‘marketisation’ of biological resources

‘Marketisation’ refers to a process in which the rules of property and contract are used to constitute free markets in given objects (property constituting the rights in the object and contract facilitating the exchange of those rights). In the case of biological resources the process of marketisation has been dramatically advanced and globalised by TRIPS and the CBD. A revised IU will further contribute to this process.

The CBD recognises the rights of states over genetic material. As part of their sovereignty states can create rules of property, access and contract relating to that genetic material. Importantly, rules that prohibit the market exchange or transfer of genetic resources would run the risk of being counter to the objectives of the convention (see Article 15(2) of the CBD).

The process of marketisation that the CBD establishes is limited in that:

1. the CBD does not apply to human genetic materials
2. the CBD only applies to genetic resources that are provided from in-situ conditions or that have been acquired in accordance with the CBD (this has the effect of excluding genetic resources in *ex situ* collections not acquired in accordance with the CBD).

COP3 recognised that the regime developed under the CBD was not well-suited to genetic resources for food and agriculture and remitted discussion of these to FAO and the negotiations on the IU revision to bring it into line with the CBD. One of the objectives of this is to create a more open area for exchange of materials relevant for food and agriculture under a regime that retains at least some elements of the common heritage approach, which has been the basis of development in this area. Policy makers outside of agriculture whose decision-making impacts on agriculture will need to develop a better understanding of this sector:

Agriculture is unique because of its diversity and location-specific requirements, necessitating adaptation of technologies to a range of agroecological conditions. A large number of poor

households in developing countries derive their livelihood from resource-poor areas with difficult agro-climatic conditions. Ensuring their access to technologies is therefore crucial for poverty alleviation¹⁰⁵.

2.1.3.2. Human genetic materials

Even though the CBD does not apply to human genetic materials such materials may be the subject of patent applications provided that they meet the criteria of invention. TRIPS does permit states to enact a morality criterion in their patent law, but the scope of this criterion in patent law has to date been narrowly interpreted.

2.1.3.3. Ex situ collections outside of the CBD

By Resolution 3 of the Nairobi Final Act, the CBD negotiators recognised that *ex situ* collections formed before the entry into force of the CBD are an outstanding issue, and not governed by the Convention. The bulk of the material in the CGIAR collections are in this category. There are other *ex situ* collections, including of plant genetic resources for food and agriculture, outside the CGIAR, in public or private hands. The International Network of *Ex situ* Collections under the Auspices of FAO, include not only the CGIAR collections, but other material, such as the regional coconut collections of COGENT. This Network is under Article 7 of the IU. Article 7.1(a) requires that such a network operate on the principle of unrestricted exchange of plant genetic resources.

The most important *ex situ* collection of plant germplasm for food and agriculture is that held by the members of the CGIAR system. In 1994 members of the CGIAR and the FAO concluded an agreement that placed 'designated germplasm' under the auspices of the FAO. Under the terms of that agreement each Centre holds the designated germplasm "in trust for the benefit of the international community" (see Article 3(a) of the Agreement). Centres are obligated not to claim legal ownership over the designated germplasm or seek any intellectual property rights over it (see Article 3(b)). When a Centre transfers designated germplasm to a third party it must make sure that that party is bound by the same conditions relating to ownership and intellectual property that apply to that Centre. The Agreement creates in effect an international common pool for designated germplasm with the following restrictions:

- the trust obligation relates only to designated germplasm and not all the biological resources that a Centre may hold.
- the obligation to ensure that the designated germplasm does not become the subject of intellectual property rights does not apply to states that repatriate germplasm that they have provided
- the Centres face a problem when it comes to enforcing the terms of the Material Transfer Agreements they use¹⁰⁶;
- new accessions can only be given the status of designated germplasm if they are free of legal restraints in the first place¹⁰⁷;
- the common pool of designated germplasm that is constituted under the FAO/CGIAR agreement does not prevent cells, organelles, genes or molecular constructs derived from that germplasm from being patented, provided that the relevant CGIAR Centre gives permission¹⁰⁸;

¹⁰⁵ W.Lesser *et al* , 'Intellectual Property Rights, Agriculture, and the World Bank' in U. Lele, Intellectual Property Rights in Agriculture: The World Bank's Role in Assisting Borrower and Member Countries, The World Bank, Washington DC, 2000, 1.

¹⁰⁶ This has been recognised by the FAO and the CGIAR Centres in the 'Second Joint Statement of FAO and the CGIAR Centres on the Agreement Placing CGIAR Germplasm Collections under the Auspices of FAO'.

¹⁰⁷ See 'Guidelines for the Designation of Accessions under the FAO Agreements'.

- the common pool of designated germplasm can be used to develop proprietary products under UPOV¹⁰⁹.

The previous section also revealed that the IU in its present form somewhat downplays the role of the principle of common heritage when it comes to plant genetic resources. A new IU regime will probably diminish the role of the common heritage principle even further by creating a multilateral system of access for a restricted number of crops for the purpose of research, breeding and/or training (See Draft Article 13.2). Other uses of that material would be worked out under the bargaining model that is endorsed by the CBD.

2.1.4. Implications of legal analysis

TRIPS itself has made a monumental contribution to the globalisation and harmonisation of intellectual property rights. One hundred and thirty six countries are now members of the WTO and are, therefore, obliged at some point to implement the provisions of TRIPS. TRIPS lays down the minimum standards that are now the starting point for bilateral and regional free trade negotiations on the protection of intellectual property. Such negotiations are continuing apace, being mainly driven by the EU and the US. Significantly countries like India that had previously been critics of higher standards of intellectual property protection are now more or less fully integrated into a globalised system of intellectual property protection.

The CBD is contributing to rather than detracting from the propertisation of the biological commons. Property rights alone do not guarantee that mutually beneficial exchanges will take place between individuals. Exchange also depends on a suitable regime of contract rules. The CBD has contributed to the development of a contractual regime for biological resources by triggering the development of access regimes by states. The CBD has also led to emerging *sui generis* regimes of national intellectual property rights in indigenous knowledge related to the biological diversity. Very few biological resources or knowledge will fall outside of the bargaining process of the CBD. Access to plant germplasm of the kind first envisaged under the principle of common heritage under the IU will be limited only to that germplasm covered by the multilateral system and then only for limited purposes. Access to biological resources covered by intellectual property rights will be dependent upon bargaining with compulsory licensing and/or competition law playing a very restricted role.

The most striking imbalance between the CBD and TRIPS lies in the unique enforcement mechanism built into one, TRIPS, while the other operates in the same way as many international treaties, by means of dialogue and cooperation. The relative imbalance in the legal clout of the two is leading to pressures to add more issues into the WTO/TRIPS regime and detracting from the necessity of effectively implementing the other. It is, then, the various practical implications and policy conflicts involved in implementing the different treaties that fire the growing debate about changes in this area.

¹⁰⁸ See 'Guiding Principles for the Consultative Group on International Agricultural Research Centres on Intellectual Property and Genetic Resources'.

¹⁰⁹ See 'Guiding Principles for the Consultative Group on International Agricultural Research Centres on Intellectual Property and Genetic Resources'.

2.2. The practical and policy relationships

2.2.1. Overview

Our interview data confirms what is already publicly evident, namely that the extension of intellectual property rights through TRIPS is being seen by many groups as a threat to their interests. A legal analysis that concludes that TRIPS does not create problems for the CBD regime largely misses the point - the simple truth is that people can feel that their interests are being threatened in the absence of a direct violation of their rights. Our data also points to a loss of trust in this area of decision-making. As one interviewee, speaking of the extension of intellectual property rights to living systems, put it - "why should we make ourselves vulnerable" [to developed country interests]. TRIPS, as another interviewee observed, is seen by many developing countries as a tool for developed countries. The perception of the basic unfairness of TRIPS runs deep. It is clear that no amount of legal exegesis and reasoning will overcome this perception. This is particularly important because, although all law making is a process of balancing interests and not some objective, mechanistic activity, the international law created in TRIPS is even more so and felt to have come out of a deeply unbalanced process by many now subject to its rules.

While the two key texts may not conflict in a legal sense, policy conflicts do arise out of their existence and implementation. These emerge from differing values relating to social and economic concerns. These have been grouped below under a number of headings, in keeping with our TOR. Other issues, however, such as health impacts, technology transfer, are also of concern to various actors and may also affect their view of the issues dealt with below.

The range and depth of concerns about these legal instruments raised by those stakeholders with different views (eg, NGOs, business organisations) stem from some fundamental differences on the nature and direction of sustainable human development. It is these deeper underlying issues that have and will continue to fire the debate and policy conflict over the implementation of both the CBD and TRIPS agreements, no matter what the legal interpretation may be.

For some (mostly the NGOs), they take human development in the wrong direction and misunderstand the nature of the ecological relationships upon which sustainable development must be built. For others (especially business), they offer many opportunities to harness human creativity and use new technology to extend development of new goods and services in a globalised market, which will in turn increase wealth generation and overall well-being. The latter believe any adverse environmental or social problems arising from these developments can and will be dealt with by innovative technological and social developments, whereas those opposing them do not.

A number of conflicts arise from a failure to sufficiently address the distinction between agricultural biodiversity (agrobiodiversity) and non-cultivated, (wild) biodiversity and the ways in which these two forms of biodiversity matter or not as the case may be to the food sector, the agricultural sector, the alternative medicine sector and the pharmaceutical sector to name some key ones. Indeed, the COP to the CBD have recognised an aspect of this problem by derogating to the negotiations at FAO on the IU the responsibility for developing a multilateral system for dealing with genetic resource for food and agriculture which retains some of the common heritage features abandoned in the CBD.

The CBD seems to have developed from a natural resource, mining mentality – in which developing countries, as evidenced in a number of comments we had, felt they had undervalued wild biodiversity of use to developed countries and major industries, such as pharmaceuticals, from which they could

seek returns. But those we spoke to involved in the agriculture sector thought that the mining, winner-takes-all mentality that the CBD seems to have stimulated in relation to the exploitation of wild biodiversity pays scant attention to the differing nature of agricultural genetic resources which have been developed, exchanged and mixed up around the globe for millennia. Indeed, 'wild' biodiversity rich countries like Brazil, are agriculturally biodiversity poor, as more than one interviewee noted.

2.2.2. Social and cultural development

One set of policy conflicts arises because of differing views about the basis of social and cultural relations related to differing social and cultural values. While most commercial and government actors do not have problems with the developments, a range of religious, ethical and spiritual concerns have been raised about TRIPS and biodiversity-related issues mainly by NGOs, indigenous groups and religious organisations. These arise from a different understanding of human and environmental relationships from those embodied in the TRIPS and CBD. Both agreements, the preamble to the CBD notwithstanding, are as we saw in an earlier section (see 2.1.3.1) centrally involved in the marketisation of biological resources. They give little or no value to the intrinsic value of biodiversity but focus on instrumental value of biological and genetic resources for human use. Other concerns arise from the growing practice in the leading IPR states, linked to new technology, to include living organisms and parts thereof in the IP system. Some respondents only acknowledge the religious concerns (these tend to be industrialised countries, institutions which favour the 'market economy' system) and dismiss any others.

2.2.2.1. Intrinsic ethical concerns

In the TRIPS agreement, a fundamental ethical problem is raised by the extension of IPRs into biological materials, which is mandatory in the case of micro-organisms and plant varieties and optional for plants and animals.

This raises intrinsic matters of principle about the treatment of living organisms. These include religious objections to extending patentability to life-forms as fundamentally mistaken. Some argue that they are not human inventions, even if modified in some way, others that use of IPRs involves treating life as a commodity, and should be rejected as such.

For some indigenous peoples with different values and attitudes to the use, ownership and sharing of knowledge, application of IPRs to their way of living itself poses a threat to that way of living. Indeed, one federation of Indigenous Peoples reportedly began their statement on this issue like this:

*"Humankind is part of Mother Nature, we have created nothing and so we can in no way claim to be owners of what does not belong to us. But time and again, western legal property regimes have been imposed on us, contradicting our own cosmology"*¹¹⁰

Gurdial Singh Nijar, a lawyer in the Third World Network, also argues that "the Western, industrial model of innovation is...antithetical to the ethical and social values and needs of many Third World Countries and peoples." He suggests that "to provide any kind of 'protection' of rights is to bring indigenous peoples and local communities and their resources into the fold of the market economy,

¹¹⁰ Quote in Someshwar Singh, "Traditional Knowledge under commercial Blanket", SUNS no 4545, 5 Nov 1999 (<http://www.twinside.org.sg/>)

which with its subversive influences of materialism and consumerism, could overwhelm and ultimately destroy these societies...¹¹¹.

Such a destruction itself would be a contravention of the CBD if biodiversity is understood in a broad sense and includes the great diversity of human societies. If the developing regulatory framework runs counter to the ability of indigenous peoples to flourish, as examples of biodiversity within the human species, then it will be failing.

Yet indigenous peoples are being pushed into taking defensive measures to protect 'their' knowledge - in part by the extension of IPRs, in part by a sense of having existing knowledge or genetic resources being usurped by others without any recompense. This lies behind the pressures to develop some form of protection for communal knowledge and to ensure benefits from its use flow back to the communities in question¹¹². The universal application of western property law, through IPRs in TRIPS, is likely, then, to affect the social and cultural mores of indigenous people unless governments "maintain an open mind and be more daring in exploring ways and means to protect and promote indigenous and traditional knowledge outside of the dominant IPR regimes"¹¹³. For the time being at least there are no concrete regulatory proposals being put forward for the effective international protection of indigenous knowledge. Its status remains that of an agenda item and 'talkfest' topic. This in turn causes the perception amongst indigenous groups that when Western policy makers talk about the issue they are engaged in a dissembling rhetoric designed to placate, but not deliver. A regulatory proposal that addresses some of the concerns of indigenous groups in this area is for a Global Bio-Collecting Society.

A range of Christians, Catholic and Protestant, also reject the extension of IPRs into living organisms as wrong in principle. Both the Church of Scotland and an Association of Catholic Development Agencies (CIDSE) have issued reports opposing the patenting of lifeforms and urging that other mechanisms be found to deal with rewarding innovation in this area¹¹⁴. They regard the extension of the term invention to cover living organisms as a legal fiction, with the Church of Scotland statement arguing:

"An animal, plant or micro-organism owes its creation ultimately to God, not human endeavour. It cannot be interpreted as an invention or a process, in the normal sense of either word. It has a life of its own, which inanimate matter does not. In genetic engineering, moreover, only a tiny fraction of the makeup of the organism can be said to be a product of the scientists. The organism is still essentially a living entity, not an invention. A genetically modified mouse is in a completely different category from a mouse trap."

¹¹¹ Gurdial Singh Nijar, "In Defence of Local Community Knowledge and Biodiversity: A Conceptual Framework and the Essential Elements of a Rights Regime", Third World Network, Paper 1, 228 Macalister Road, 10400 Penang, Malaysia, 1996.

¹¹² Geographical indications in developed countries, do effectively recognise cultural properties (wines in particular) without there being an individual owner of such rights, but, to date, such models have not been considered in CBD forums.

¹¹³ Victoria Tauli-Corpuz of the Tebtebba Foundation, an international indigenous people's research centre based in the Philippines quoted in Somewshwar Singh, "Traditional Knowledge under commercial Blanket", SUNS no 4545, 5 Nov 1999 (<http://www.twinside.org.sg/>)

¹¹⁴ Donald Bruce & Ann Bruce, *Engineering Genesis – The Ethics of Genetic Engineering in Non-human Species*, Earthscan, 1998, chapter 10 examines both sides of the case for and against patenting lifeforms. See also CIDSE Biopatenting and the Threat to Food Security – A Christian and Development Perspective, International Cooperation for Development and Solidarity, Brussels, 2000.

There is no agreement across the various denominations, or even within some of them, on this. However, even those who accept patenting in principle have concerns about its possible implications. One concern that has both intrinsic and extrinsic or consequential elements is the role patenting plays in what Donald and Anne Bruce call the commodification of life. Intrinsically, it is seen as an undesirable thing socially as it undermines the value of life and reduces it to a mere object.

2.2.2.2. Consequentialist ethical concerns¹¹⁵

Other objections are based on the possible consequences patenting living organisms might have. In a recent report, for example, CIDSE argues that there are limits to the importance of a commercial reward for inventiveness and that if the exercise of patent rights results in diminishing or denying basic health, food or livelihood needs of poor people then they should be rejected. This is one aspect of opposition to IPRs which is based on assumed or expected negative economic, social and cultural effects on key groups such as poor farmers in developing countries who may be marginalised. Others object to IPRs because of their perceived role in the promotion of globalisation, the concentration of economic control over agriculture and health care products, and encouragement of genetic engineering.

2.2.3. Economic Issues

Most industries involved in this area argue that strengthening IPRs will bring benefits to the economy through enhanced innovation and development of useful new technologies. They see the consequences as good as this increases wealth which will improve human welfare and allow environmental concerns to be tackled. They also strongly oppose, on economic and moral grounds, conditions that permit either counterfeiting of goods or free-riding, ie, the use of processes and skills developed by others without payment to them. It was on the basis of combating production of counterfeit goods that TRIPS was originally sold to the developing countries and a strong case made against piracy of corporate designs and products. The extension of IPRs into the biological arena, however, has led to accusations of a reverse form of piracy – biopiracy – by both developing countries and NGOs¹¹⁶.

2.2.3.1. Effects of IPRs

The most common justification for IPRs related to the origination of new products is that the exclusivity that they confer (the exclusivity being defined differently for each kind of right) contributes to the dynamic efficiency of the market in invention and innovation. The empirical evidence that patents, for example, actually function in this way or function in a way such that costs exceeds benefits is much less clear cut. Recent economic work suggests that tacit knowledge flows are far more important to invention and innovation than realised¹¹⁷. The patent system, it would seem, makes little contribution to such flows and in fact may inhibit them. One implication of this research is that the markets in invention may not be subject to the degree of market failure first thought. Related to this is the view that the costs of the patent system may be much greater than we realise. Broad patents, which are more or less inevitable in new areas of technology, may slow research. Since, from a social welfare point of view, it is diffusion of the invention that matters most there is a strong argument that we ought to be concerned with protecting follow-on research¹¹⁸. The policy upshot of this analysis is that we

¹¹⁵ For a consequentialist analysis of intellectual property see P. Drahos, *A Philosophy of Intellectual Property*, Dartmouth, 1996.

¹¹⁶ See Action Aid, "Trade-Related Intellectual Property Rights (TRIPS) and Farmers' Rights", Nov 1999

¹¹⁷ See T. Mandeville. *Understanding Novelty: Information, Technological Change and the Patent System*. Ablex, 1996.

¹¹⁸ For a discussion of these issues see J. Barton, 'Patents And Antitrust: A Rethinking In Light Of Patent Breadth And Sequential Innovation', 65 (1997) *Antitrust Law Journal*, 449.

should be thinking about weaker and not stronger patent protection. Clearly, a balance is needed between the benefits to society from granting IPRs and the costs.

Former CIEL lawyer David Downes and others argue that it is this balance that is wrong in the relationship between TRIPS and biodiversity. "This balancing must take into account that the right is a time-limited exclusive right to control commercial use and sale of a valuable product -- a right which allows the holder to raise price and to reduce supply of the patented product to consumers. Patents on inventions that are particularly improved or innovative may confer market dominance or even a monopoly to the owner. Thus, the scope of these exclusive rights – in terms of time, technology covered, activities covered and geographical application – must be carefully defined to maximise benefits to society through a balancing of interests in stimulating innovation, avoiding excessive market dominance, and maximising the free availability and exchange of information needed for a creative, innovative, and equitable society"¹¹⁹.

In reality, the relative costs and benefits of IPRs on development are generally unclear¹²⁰. So far as trade is concerned it is clear that technology importing countries have very little to gain from shifting to higher international standards of intellectual property protection than already exist¹²¹. TRIPS has extended the system of IPRs to a huge number of countries very rapidly. This is unlike most developed countries' experience. Most tended to copy from the market leaders in technology and reached a certain level before adopting IPRs. The development value of universal minimum levels of IPR protection for developing countries has been seriously questioned by academics and development agencies, official and voluntary. The former chief economist of the World Bank, Joseph Stiglitz, and the UN Development Programme in its 1999 Human Development Report have warned against ever tighter rules governing intellectual property. Indeed, UNDP argued that "the relentless march of intellectual property rights needs to be stopped and questioned"¹²².

The 'relentless march of intellectual property rights' has occurred in biotechnology, with patents being granted on basic research tools and important genomic information. John Barton has observed that "people are obtaining patents on tools such as partial gene sequences or research mice, and allowing their use only in return for rights in any final products developed with them"¹²³. There has been something of a patent frenzy in biotechnology in recent years, which has seen :

1. Japan and the United States securing "rights to 70% of EPO patents for human gene sequences"¹²⁴;

¹¹⁹ David Downes, "The 1999 WTO Review of Life Patenting Under TRIPS, Revised Discussion Paper", former CIEL lawyer, Washington DC, November 1998.

¹²⁰ See World Bank, Knowledge for Development - World Development Report 1998/99, OUP, 1998, web: <http://www.worldbank.org>, and for a short summary G. Tansey, Trade, Intellectual Property, Food and Biodiversity: Key issues and options for the 1999 review of Article 27.3(b) of the TRIPS Agreement, Quaker Peace & Service, London, Jan 1999.

¹²¹ For a general discussion of the trade issues see B. Lyons, 'International trade and technology policy' in P. Dasgupta and P. Stoneman (eds) Economic policy and technological performance Cambridge University Press, Cambridge, 1987, 169-205; A. Subramanian, 'The International Economics of Intellectual Property Right Protection: A Welfare-Theoretic Trade Policy Analysis' 19 (1991) World Development 945-956. For an example of literature that deals with the impact of the patent system on a medium sized technology-importing country see The Economic Implications Of Patents In Australia, Australian Patent Office, Canberra, 1981; Industrial Property Advisory Committee, Patents, Innovation And Competition In Australia, Australia 1984.

¹²² UNDP, *Human Development Report* 1999, OUP, 1999

¹²³ John Barton, Reforming The Patent System, *Nature*, 2000

¹²⁴ S. Thomas *et al*, 'Ownership of the human genome', *Nature*, 4 April 1996, 387.

2. US companies developing “aggressive” patenting strategies in relation to genomic information and European multinationals responding by investing in the dynamic US SME biotechnology sector in order to gain access this information¹²⁵.

The impact of high levels of biotechnology patenting on the different markets in which genomic information is or will be relevant is essentially a matter of guesswork. However this guesswork can be informed by different kinds of studies including, for example, an examination of the licensing practices of companies in different sectors such as pharmaceuticals and agrobiotech. Here it is worth noting that patent licensing strategies have been poorly studied. The consequences to market structure of different strategies of patent blanketing, fencing, surrounding is at an empirical level far from well understood¹²⁶.

Large companies, often originally chemical companies, such as Du Pont that now present themselves as ‘life sciences’ companies have developed a patent tradition and culture that stretches, in some cases, back to the beginning of the last century. They have a matchless expertise in the use of patents as a weapon of business that covers many of the last century’s most important technologies. This patent driven business culture will bring with it profound changes in areas such as public sector plant breeding.

The growing rise in the number and use of biotech patents raises issues of market power in agricultural and food markets, the effect of such patents on research, the ability of different countries to compete in world markets, environmental sustainability, and agricultural biodiversity. We briefly deal with each in turn below.

2.2.3.2. Market structure and power

An historical perspective on the use of patents may give some idea of the kind of market structure likely to dominate in a biotech seed industry of the future underpinned by strong IPRs. Technological innovation has long been seen as a way of entering an industry, and patent-protected innovation used as a means of gaining legal quasi-monopolistic control of certain products and sectors of an industry. While this a relatively new phenomenon in the biological sphere, it occurred in the 19th century, for example, with inventors like George Eastman (Kodak) and the photographic industry, where he sought patents to capture monopoly profits as Reese Jenkins notes in his study of Kodak¹²⁷. Similarly, in the twentieth century the chemical industry and the pharmaceutical industry used patent agreements to establish international cartels. Synthetic hormones and quinine are examples of essential medicines the supply of which was affected by these cartels¹²⁸. The point is that the same industries (and in some cases the same companies) that have a long historical experience in using the patent system to run international cartels are now seeking patents in relation to genomic information and may, using those patents, seek to create similar kinds of industry structures in those markets where genomic data will be the basis of essential products. In this context is worth noting the concerns expressed about market structures by some recent studies:

¹²⁵ See S.M. Thomas and N. Simmonds, *The Industrial Use of Genome Resources in Europe*, European Commission, DG Science, Research and Development, 1999.

¹²⁶ O. Granstrand, *The Economics and Management of Intellectual Property*, Edward Elgar, 1999, 219-221.

¹²⁷ Reese Jenkins, “Images and Enterprise: Technology and the American Photographic Industry 1839 to 1925”, Johns Hopkins University Press, 1975.

¹²⁸ Ervin Hexner, *International Cartels*, London, 1946, 308-339.

The Nuffield Council observed that there were “six major industrial groups who between them control most of the technology which gives the freedom to undertake commercial R&D in the area of GM crops. These are:

- Agrevo/Plant Genetic Systems,
- ELM/DNAP/Asgrow/Seminis,
- Du Pont/Pioneer,
- Monsanto/Calgene/Delkalb/Agracetus/PBI/Hybritech/Delta and Pine Lane Co.,
- Novartis,
- Zeneca/Mogen/Avanta¹²⁹.

A recent House of Lords report in the UK also warned of the problem of cartels and monopolies in the agrochemical/seed sector, pointing out that the degree of consolidation was already much greater than in the pharmaceutical sector¹³⁰.

A 1997 study by Krattinger in Bt patents showed that the then six major company groups held about 60% of the 410 patents which related to the Bt gene and Bt pesticide technology¹³¹. As Krattinger pointed out, this patent ownership also effectively sequestered research on the manipulation of cry proteins, which have selective application to the various agricultural pests.

A study of agricultural biotechnology for ISNAR in the early 1990s found that “Companies now seek protection through IPR in more countries than they did in the past in order to (i) expand their market share, (ii) prevent competitors from becoming active in those countries, or (ii) as a bargaining tool to negotiate favourable local agreements”¹³².

The World Bank noted in its 1998 World Development Report, “So many industrialised country firms are acquiring strong intellectual property positions, often covering fundamental research tools as well as marketable products, that it may prove hard for new firms and researchers to elbow into this new global industry”.

The issue is not just about markets and market power, however, but about the nature and direction of R&D and who will get what benefits to emerge from it¹³³.

2.2.3.3. R&D

The impact of concentrated markets in genomic information and tools on public sector and private sector research programmes, especially in developing countries, may well be considerable. Companies holding patents over key biotechnologies may wish to service expanding developing country markets themselves. They may be reluctant to license use of key biotechnologies to public sector research programmes in developing countries if there is a risk that those programmes use the licensed technology to produce agricultural products as a public good for their agricultural sector. The

¹²⁹ Nuffield Council on Bioethics, *Genetically Modified Crops: The Ethical and Social Issues*, 1999, para 3.36.

¹³⁰ Select Committee of the House of Lords, *EC Regulation of Genetic Modification in Agriculture*, 1998, para 85.

¹³¹ A.F. Krattinger, *Insect Resistance in Crops: A Case Study of Bacillus thuringiensis (Bt) and its Transfer to Developing Countries*, Ithaca, NY, ISAA Briefs No 2, 1997.

¹³² Jeroen van Wijk, Joel I Cohen and John Komen, “Intellectual Property Rights for Agricultural biotechnology – Options and Implications for Developing Countries”, ISNAR Research Report 3, The Hague, 1993

¹³³ See the recent paper by Simon Walker, “The TRIPS Agreement, Sustainable Development and the Public Interest – A Discussion Paper”, CIEL and IUCN, 1999.

private ownership of fundamental biotech patents may put barriers in the way of developing countries when it comes to carrying out research related to sustainable use within the context of their own ecosystems and agricultural needs. The failure of TRIPS and the CBD to deliver tangible results on technology transfer fuels such expectations. The impact of the availability of dual protection on plant variety rights will also have to be carefully monitored, but US experience suggests that patents will predominate.

There is no clear evidence that in agriculture, IPRs positively or negatively affect R&D. Preliminary results from work underway at IFPRI do not support the idea that tightened IPRs enhance investment in R&D. Although there has been an increase in R&D in the US coincident with expanding IPRs there is no necessary causal relationship between them. Both the science underpinning agriculture and the structure of the agriculture industry itself has also changed at the same time¹³⁴. Researchers and seed industry experience, on the other hand, suggests that the flow of germplasm has reduce since the CBD came into force and that the openness of scientific exchanges have declined.

The shift in funding from public to private R&D in the agriculture sector that has taken place plus the fascination with modern biotechnology lead some, such as Hans Herren, Director General of the International Centre of Insect Physiology and Ecology in Kenya, to argue that this is skewing the R&D effort away from directions that would be of most use to small farmers and diverse agricultural systems¹³⁵.

Since the overall benefits of IPRs in general, and in agriculture, are not clear cut, there is a growing argument that the precautionary principle should be applied in their use just as much as in the use of genetically-engineered plants and animals to which they are linked¹³⁶.

International competitiveness

National governments with modern biotech industries want to ensure their firms can be competitive internationally. European life science industries argue strongly that to remain internationally competitive they need strong IPRs to be able to match the terms under which their competitors in the USA, which has the strongest IPR system for biological materials, operate. Unless they do so, then countries will lose out and investment in R&D in pharmaceuticals and biotechnology will focus in the US. There is also a pressure to ratchet up protection levels to those of the major player, the US¹³⁷ - which generates much of the IP in the world today and relies increasingly on exports with a high IPR content.

Some observers are cautious about this argument and believe that even if it is true, then it is likely not to benefit EU firms, as US firms already have a considerable head start (see Section 2.2.3.1). The patent system in particular operates on the basis of winner takes all. The US has many advantages over Europe in the race to propertise genomics information, including, as one report recently noted, a far superior small sector genomics industry: "[t]he sheer size of the US small firm sector has led to

¹³⁴ Phil Pardey, pers comm, IFPRI.

¹³⁵ Hans R Herren, "The Wishes of the Rich *versus* the Needs of the Poor: Which Biotechnologies are Appropriate for Sustainable Agricultural Production in the Tropics", ICIPE, Nairobi, Kenya, 1998

¹³⁶ On GM see the policy recommendations from the Economic and Social Science Research Council, Global Environmental Change Programme, "The politics of GM food: Risk, science and public trust". *'The Politics of GM Food: Risk, Science and Public Trust'*, University of Sussex, 1999, available on the website: www.gecko.ac.uk

¹³⁷ See P, Drahos, 'Biotechnology Patents, Markets and Morality' 1999 European Intellectual Property Review.

over fivefold the number of patent applications in genomics compared to Europe"¹³⁸. One respondent argued that strong IPRs will mean control of seeds in the future will rest with US and Swiss companies, not EU companies. It may, therefore, be prudent for European industry to consider the rules of the intellectual property game from the point of view of coming second rather than first in this particular race. This in turn would suggest investigating access issues under competition policy, licensing issues as well as reform of the patent system itself.

For many developing countries, this seems more like a struggle to determine who among the developed countries will dominate them rather than how they will be an equal partner in developing and benefiting from new technology. In the absence of both a level playing field and equally balanced teams of players, they increasingly see the need for special and differential treatment in IPRs. For some this might be through derogations from the IP requirements and / or less stringent application of them, for others the use of *sui generis* systems of protection that include indigenous knowledge, access and benefit sharing rules and not simply variety protection.

2.2.4. Environmental Sustainability

Some concerns about the effects of IPRs on biodiversity stem from a different understanding of the world based on an ecological fundamentalism. In this, no matter how people care to define what they do and how to split up the benefits from productive activity, the biosphere has its own rules which cannot be redefined away. The economic and legal arguments about the nature of IPRs and biodiversity are misplaced. Instead ecological analyses are needed to which the others should be subservient. Both the CBD and TRIPS are legal constructs, depending for their operation on legalistic debates about meaning and interpretations of rules that are essentially made up by different groups of people seeking to balance different interests. These ignore the reality that there are limits to what the various ecosystems will tolerate, in terms of human intervention, beyond which changes will take place that will destabilise the environment in which human life has developed.

Here, then, the economics are not the point. What is at issue is environmental sustainability, in a world where already climatic instability is growing due to earlier technological developments. A key problem is that that current economic thinking and calculations treat too many important factors as externalities, and so play no role in shaping commercial decision-making. Various NGOs see the move to rapidly redesign all life-forms used in food and agriculture as being underpinned by the new IPR regime. They feel that this poses an even bigger threat to biodiversity than industrialised intensive farming system, and consequently to the future food security of people on the planet and to the ecological balance. Hence there is opposition to TRIPS, notably article 27.3(b).

Different visions underlie these points of view. One embodies a technological optimist vision, built on 19th century positivism, embodied in both Marxism and capitalism. This puts people at the centre of the universe, relates all operations to their interests and assumes any problems created by technological innovation will be overcome by further technological innovation. The other, different elements of which are espoused by various NGOs, suggests a more radical rethink is needed¹³⁹.

¹³⁸ See S.M. Thomas and N. Simmonds, *The Industrial Use of Genome Resources in Europe*, European Commission, DG Science, Research and Development, 1999, 7.

¹³⁹ This is debated across many fields – two examples are Eivind Hovden, "As if Nature Doesn't Matter: Ecology, Regime Theory and International Relations", *Environmental Politics*, Vol 8 No 2, Summer 1999' and The European Ecumenical Commission for Church and Society, "The Dominant Economic Model and Sustainable Development: Are they Compatible", Feb 1996.

One problem is the impossibility of developing scientifically-based risk assessment systems given the current state of knowledge about the long-term effects of adopting new technologies on the environment and long experience of unexpected effects. 'Current approaches [to risk assessment] neglect the scientific basis for dealing with ignorance and fail to recognise that the underlying assumptions used at the start of the process of risk assessment can significantly affect the outcome' says Dr Andy Stirling, at the Science and Technology Policy Research Unit. This implies that 'politicians must take care not to portray an "absence of evidence" as "evidence of absence" of problems and risks'¹⁴⁰.

Some, such as CIDSE, also argue that there is an imbalance in the way potential environmental and economic risks are weighed, with the former seen as externalities, and so their costs fall onto society at large. They are not factored into both the economic and legal framework and not matched by a similar liability regime. Indeed, the issue of liability proved so contentious in negotiating the Biosafety Protocol that it was left to be sorted out over four years following the signing.

2.2.5. Farming systems

Some NGO concerns about the effects of IPRs on different and diverse farming systems focus on the ecological sustainability of these. A stronger IP regime is expected to promote a tendency to intensive farming systems supplied by private sector breeders with reduced levels of biodiversity. Others are concerned about the impact of IPRs in the process of generating new technology in developing countries and on small farmers. They feel patenting - gene patents and variety patents - locks up and directs agricultural research in a direction that is not small farmer friendly. Small farmers are not helped by the new technology but rather the new technologies help their competitors in more favoured areas. Although it is the CGIAR's role to redress that balance to small farmers in marginal areas, its capacity to do so may decline.

These concerns in part depend upon the vision of agriculture and the place for small farmers and those in disadvantaged areas in it. For farming systems provide livelihoods not just products and the impact of IPRs on the sustainability of the livelihoods of those engaged in agriculture today is worrying some in developing countries and in agricultural research. They fear IPRs may bolster trends which add to the rate at which many of today's small farmers in developing countries are marginalised and forced off the land. That may be all right if they want to go, if policy makers want get rid of them and if there are jobs for them, but as some interviewees made clear that was not necessarily the case.

The broader point is that technologies are not neutral nor simply tools – they embody social and power relations which benefit some and disadvantage others. Their effects extend both in space and time. The temporal dimension – with its importance for intergenerational and ecological effects – is a much neglected aspect of genetic engineering according to Barbara Adam¹⁴¹. IPRs are seen by their critics as promoting the development of genetic engineering, and an industrialised intensive approach to agriculture, likely to lead to marginalisation of poor farmers and poorer areas and also to reduce agrobiodiversity. This is disputed by the seed industry which argues that modern varieties contain within them a wide diversity of genes.

The seed industry, in Europe in particular, argues strongly that protection of plant varieties under Plant Breeders Rights, with the right to breed new varieties from protected varieties, has underpinned the

¹⁴⁰ Economic and Social Science Research Council, Global Environmental Change Programme, "The politics of GM food: Risk, science and public trust". *The Politics of GM Food: Risk, Science and Public Trust*, University of Sussex, 1999.

¹⁴¹ *Timescapes of modernity – The environment and invisible hazards*, Barbara Adam, Routledge, London, 1998.

development of the many highly-productive commercial varieties available to farmers today. These have a range of yield, disease and stress tolerances that make agriculture as productive as it is. The industry is, therefore, strongly supportive of the provisions in TRIPS 27.3(b) which requires protection to be provided for plant varieties. In general they favour use of Plant Breeders Rights as developed in the UPOV system.

Some in the industry, notably those connected with the use of genetic engineering and in the USA, support patenting as the means to secure protection of their investment in new varieties. They believe strong IPRs are needed to ensure returns on the investment required to develop future plant varieties and animal breeds using genetic engineering.

Patenting of varieties under US law does not allow for a breeder's exemption, meaning that a patented variety may not be used for further breeding, without the agreement of the patent holder. Moreover, there is a difference between EU and US regarding the patentability of plant varieties. In Europe, because of the existence of UPOV, the European Patent Convention does not permit the patenting of varieties. The European Patent Convention expressly excludes plant *varieties* from patentability.¹⁴² In 1995, a ruling of the EPO Technical Board of Appeal¹⁴³ determined that a claim for plant cells *contained in a plant* is unpatentable since it does not exclude plant varieties from its scope. This implied that transgenic plants *per se* were not patentable because of this plant variety exclusion. However, this was overturned by a December 1999 decision of the Enlarged Board of Appeal which in the Novartis case determined that "a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b), EPC *even though it may embrace plant varieties*" [emphasis added]. This determination has been interpreted to mean that the insertion of a trait is patentable in Europe, provided the patent claim does not specifically refer to plant varieties.

Some also tend to argue that the benefit sharing requirements in food and agriculture are met through the development of the new varieties themselves in their breeding programmes and that no further benefit sharing is required. However, the international seed industry association, ASSINSEL, has proposed at the negotiations on the IU that should patent protection be introduced, and result in removal of germplasm or specific genes from the breeding pool available to breeders, then some form of royalty payment to a fund devoted to safeguarding plant genetic resources for food and agriculture should be introduced.

2.2.6. Agricultural biodiversity

The concerns expressed in earlier sections of the report have a direct relevance to the continued loss of agrobiodiversity in both animals and plants, through the potential effect of IPRs on farming systems and environmental sustainability in particular. Agricultural biodiversity or agrobiodiversity results from the careful selection and inventive developments of farmers, herders and fisherfolk over millennia. It is a sub-set of biodiversity that includes:

- harvested crop varieties, livestock breeds, fish species and non-domesticated ('wild') resources within field, forest, rangeland and in aquatic ecosystems;
- non-harvested species within production ecosystems that support food provision, including soil micro-biota, pollinators and so on; and

¹⁴² The same exclusion is contained in the European Union's "Directive 98/44/EC on the Legal Protection of Biotechnological Inventions". However, the legality of this directive is being challenged.

¹⁴³ *Greenpeace v Plant Genetic Systems NV*.

- non-harvested species in the wider environment that support food production ecosystems (agricultural, pastoral, forest and aquatic ecosystems)¹⁴⁴.

Agricultural biodiversity results from the interaction between the environment, genetic resources and the management systems and practices used by culturally diverse peoples resulting in the different ways land and water resources are used for production. It thus encompasses the variety and variability of animals, plants and micro-organisms which are necessary to sustain key functions of the agro-ecosystem, its structure and processes for, and in support of, food production and food security. Its management requires approaches different from those connected with the extraction of chemicals from 'wild' biodiversity as used in the pharmaceutical industry (see 2.2.1).

Agrobiodiversity is threatened in many places through continuing genetic erosion which sees the number of plant and animal species declining – more generally there is also genetic erosion of wild species with the loss of habitats for wild plants and animals through cutting down forests (for logging or farming), urban expansion and climatic changes. Agrobiodiversity has various distinctive features, including being actively managed by farmers, requiring indigenous knowledge, and involving interdependence between countries for the genetic resources upon which our food systems are based¹⁴⁵.

The CBD has been cooperating with FAO in the development of a work programme on agrobiodiversity which includes changing agricultural practices and the “mobilisation of farming communities, including indigenous and local communities, for the development, maintenance and use of their knowledge and practices in the conservation and sustainable use of biological diversity in the agricultural sector with specific reference to gender roles”¹⁴⁶. This recognises that substantial work is needed to safeguard agricultural biodiversity, a view expressed by various interviewees.

The loss of animal genetic diversity has led to a new programme being set up at FAO over the past few years as animal breeds are disappearing rapidly¹⁴⁷. The major way to allow agrobiodiversity to continue to evolve, through adaptation to the changing environment, is through sustainable use *in situ* – which requires a range of agricultural systems in diverse environments and policy regimes that enable this. The replacement of a wide range of farmers' varieties and breeds by a narrower range of modern varieties is resulting in genetic erosion, for which *ex situ* collections, such as those of the CGIAR system, are a palliative measure. Both NGOs and some specialists fear that the developing IPRs regime underpins agricultural developments going in the opposite direction to that envisaged in the CBD¹⁴⁸.

Ex situ collections of germplasm are important in safeguarding agricultural biodiversity, though they cannot maintain evolutionary processes, with the collections held in trust by the CGIAR and subject to negotiations in the IU an important resource. Although these collections are not of immediate

¹⁴⁴ This particular definition is taken from the UKabc web page which deals with agricbiodiversity and has links to a wide range of sources in international organisations and NGOs: <http://ds.dial.pipex.com/ukfg/ukabc.htm>. Fuller definitions and discussion of the topics here are found in and in FAO, “Background Paper 1 - Agricultural Biodiversity”, for the FAO/Netherlands Conference on the Multifunctional Character of Agriculture and Land.

¹⁴⁵ Elizabeth Cromwell, “Agriculture, biodiversity and livelihoods: issues and entry points” ODI, London, April 1999

¹⁴⁶ UNEP/CBD/COP5/11, “Agricultural Biological Diversity: Review of Phase I of the Programme of Work and Adoption of a Multi-year Work Programme”, Feb 2000 (available on CBD website).

¹⁴⁷ Janet Raloff, “Dying breeds: Livestock are developing a largely unrecognised biodiversity crisis”, Online Science Reports, Oct 2 1997.

importance for commercial breeders they do need to be maintained as a public good according to those in the industry. Some preliminary research findings from IPGRI based on an analysis of the origins of genetic materials used in applied genetics research reported in four journals suggest that about 80% of this originates from gene banks and about 20% from collections in the field¹⁴⁹.

The changing market structure with consolidation of firms involved in breeding – both plants and animals – is also leading to a loss of some species. One interviewee argued that industry consolidation can produce determined action against the conservation of genetic resources, using examples from the US. There were 480 genetic lines of poultry in US 15 years ago (meat, eggs, chicken & turkey) selected for all sorts of traits. Now 227 have gone and another 200 or so at high risk. With company buy-outs, the number of companies involved is failing, and the lines are being destroyed as a company buys up another company, then slaughters / destroys all their genetics, unless they are of short term use in the breeding programme so they can take over the clientele. This provides a cheaper way of gaining market share than seeking out IPRs worldwide.

2.2.7. Flexibility in implementation

Within the framework of the TRIPS Agreement itself the negotiators appear to have left some room for the application of the standards contained in it. Unlike the CBD, in which the terms used are defined within the agreement (see Appendix 2), there are no definitions of the key terms in TRIPS. This provides countries with some flexibility in the implementation of TRIPS standards. This flexibility reflects the territorial nature of patents systems – the rules governing patents are decided upon by individual nations according to their needs and have considerable differences. However, as time proceeds and disputes arise between WTO Members some of this room for flexibility is likely to be reduced as rulings under the Dispute Settlement Mechanism will provide guidance on the interpretation of different terms.

Clearly, there is pressure from industry in the USA, the EU and Japan for a more harmonised approach to the interpretation of the rules and meanings of words, especially covering the growing fields where modern biotechnology plays a part. Indeed, the patent practices in the US, the EU and Japan show that “the differences with regard to patenting of biological materials have significantly narrowed down in those jurisdictions”.¹⁵⁰ However even as amongst these three major patent jurisdictions harmonisation has not been achieved. There remain, for example, differences on basic issues such as the way in which novelty is to be assessed. Wider state practice in the area of patent law also suggests that states are prepared to go only so far in the harmonisation of patent law (see, for example, the approach to the definition of discovery in the patent laws of Argentina, Brazil and the Andean Pact groups of countries¹⁵¹).

Pressures to use TRIPS as a tool to harmonise patent laws to developed country standards seem likely to cause strong reactions in a range of developing countries. TRIPS will have to be read in the

¹⁴⁸ See the FAO paper on Agricultural Biodiversity which calls for a range of policy changes and Hope Shand, *Human Nature: Agricultural Biodiversity and Farm-based Food Security*, RAFI, 1997.

¹⁴⁹ T. Hodgkin, Personal communication

¹⁵⁰ Carlos Correa, *Intellectual Property Rights, the WTO and Developing Countries – The TRIPS Agreement and Policy Options*, Zed Books and TWN, London and Penang, 2000, p 178.

¹⁵¹ Ibid, Correa also points out that the obligation to grant patents on microorganisms may be interpreted “as applicable only to genetically modified microorganisms, and not to those existing in nature”. Moreover, the scope of the definition of microorganism varies in different jurisdictions. Correa suggests it may be restricted to only include viruses, algae, bacteria, fungi and protozoa.

light of the principle of national sovereignty over intellectual property systems. If insufficient attention is paid to this principle public concerns about TRIPS will continue to grow.

2.3. Some practical impacts on policy

The policy environment for the development of regulation governing IPRs and biodiversity related issues is increasingly complex. The various legal instruments agreed or under negotiation deal with an interconnected set of activities, with changes in one area likely to have significant impacts on others as the new rules are implemented in concrete market conditions. Although the relationship between TRIPs and the CBD, and more generally, biodiversity, is hotly contested, the evidence is lacking to come down firmly on either side of many of the arguments outlined above. Some issues cannot be agreed – since they stem from completely different world-views. Others, in time, will produce evidence of effects – by which time, in the view of some, it will be too late if the effects turn out as they fear.

Until recently, development of IPRs happened among a relatively small specialist community closely linked to the beneficiaries of the rights concerned. Debates have tended to turn on legal issues and technical details. As the scope of IPRs has extended into new areas, in particular lifeforms, and the geographical coverage extended through TRIPS, wider public interest in them has greatly increased. This has long been the case with the two other areas that overlap – the environment and food and agriculture – where a broad range of interests and civil society groups have played an active role in policy making¹⁵².

As the importance of IPRs for development, environment and culture has become more widely understood the spotlight has begun to fall on their purpose, effects and legitimacy. IPRs create new forms of property. Property, it needs to be remembered, is a key institution, perhaps *the* key institution, of social and political morality. Its definition affects resource distribution and takes us straight into issues of social justice.

IPRs are not technical matters but concern crucial questions of economic interest, business competitiveness, market power, environmental sustainability, human development, human rights and ethical norms. Their framing and use will affect a wide range of national, regional and international development objectives. These include targets to reduce and eliminate hunger and poverty, safeguard the environment, halt the loss of biodiversity, empower women, and ensure food and social security.

The objective of new rules and regulation in this area is to ensure such outcomes meet broad public interests, not narrow sectoral ones. This requires a transparency in policy formulation, implementation and evaluation that is perhaps unusual in this area and difficult to achieve. Where outcomes are so contested trust requires transparency, appropriate policy instruments and institutions and adequate information about the effects of changes. This may require some rethinking of the current relationships between international institutions, the collection of the different data – from trade statistics able to show how trade between private actors is occurring, to indigenous knowledge and agrobiodiversity databases.

It also requires clearly distinguishing those things serving the public good – be they international agricultural research or the rules governing IPRs– and those serving narrower private interests, so that there is a harmony between them. This requires broad involvement of all sectors of society in shaping and framing the rules under which they operate and providing mechanisms to change those rules if

¹⁵² John Braithwaite and Peter Drahos, *Global Business Regulation*, Cambridge University Press, 2000.

they produce undesirable outcomes. This will partly come about through a wide, but not necessarily comfortable, involvement of citizen groups, business, and NGO's both nationally and internationally.

Unfortunately, most governments are poorly organised to be effective in policy making over plant genetic resources for food and agriculture, as a new report documents¹⁵³. The complexity of the negotiations themselves at the international level, with responsibility falling in different fora, is part of the problem. There is insufficient communication between those involved in different fora – a situation our own interviews have also illustrated. Another major problem is the variety of ministries involved in national capitals, where there is often a lack of coherence in policy making and insufficient attention to the important issues raised at sufficiently high a political level. This also leads to inconsistencies in the positions taken by the same national government, from both developing and developed countries, in different fora. Most immediately, argue the authors, this threatens the ability of international research centres “to produce international public goods” based on conserving and using genetic resources.

Post Seattle, different groups of actors are trying to mobilise their supporters to deal with the fall out. Some from the business and industrial country policy circles are reportedly considering how to de-legitimise the NGOs that are deemed to have caused them trouble and be anti the WTO and trade liberalisation. They are also reportedly seeking to undermine their funding base, especially those funds received from governments and foundations.

Within the NGO community, there is a move to establish a substantial follow-up campaign post Seattle to reform the international trade agenda to take into account of a broader range of issues raised by them. This will have the aim of shrinking the range of issues being dealt with by WTO and may include demands to prohibit the patenting of life forms in all national and international regimes and to remove the Trade Related Intellectual Property Rights Agreement (TRIPS) from the WTO on the basis that:

- there is no basis for inclusion of intellectual property claims in a trade agreement;
- the TRIPS agreement:
 - promotes monopoly by transnational corporations;
 - prevents access to essential medicines and other goods;
 - leads to private appropriation of knowledge and life forms;
 - undermines biodiversity; and
 - keeps poorer countries from increasing their levels of social and economic welfare and developing their technological capacity.

The basis for future development in this area should not be dirty tricks campaigns but engagement with the issues raised and seeking evidence to inform decisions about appropriate policies to follow balancing the expected costs and benefits and capacity of those expected to bear the costs to do so.

The different legal nature of TRIPS and the CBD – with the CBD providing a framework within which states can act to fulfil its objectives and TRIPS providing legal minimum standards that must be enacted in national law, with an enforcement mechanism and sanctions available for non-compliance under WTO rules – is producing pressures to push more and more activities into the WTO because its

¹⁵³ Michel Petit, Cary Fowler, Wanda Collins, Carlos Correa and Carl-Gustaf Thornstrom, “Why Governments Can’t Make Policy - The Case of Plant Genetic Resources in the International Arena”, draft presented at the Global Forum on Agricultural Research in Dresden, Germany, on May 20-21, 2000.

rules have teeth. This raises questions about the nature of the international policy environment and role of the different institutions, such as the EU.

For the EU, as a large, influential player with members who have differing views on some of the issues involved, this debate poses a number of challenges, both short and long-term. These revolve around the balance between the public/private costs and benefits from current technological changes linked to IPRs and biodiversity. The final part of this study (Section D), discusses specific policy options and priorities in this area.

SECTION C

3. Provision of technical and financial assistance

This Section identifies initiatives on IPRs and biodiversity where certain EU Commission Directorates and a sample of Member States provide technical and financial assistance to developing countries. This element of the study involved establishing the technical and financial support and initiatives provided to developing countries in:

- the promotion of international technical and scientific cooperation to developing countries under Article 18 of the CBD (the cooperation should give special attention to the development and strengthening of national capabilities by means of human resources development and institutional building);
- the provision by developed countries of financial resources to enable developing countries to meet the costs of implementing measures which fulfil the obligations of the CBD (Article 20 of the CBD);
- funding provided under Article 67 (technical and financial cooperation) of the TRIPS Agreement.

3.1. General requirements

3.1.1. Under TRIPS

The only provision giving responsibilities to developed countries for technology transfer is Article 66.2. This Article requires that “developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base”.

The TRIPS Council is currently reviewing the action that has been taken by Members to fulfil these responsibilities. Only a few countries have responded so far including Austria, Denmark, Finland, France, Germany, the Netherlands, Spain, Sweden, the UK, Ireland, Japan, Australia, New Zealand and the US. Some respondents have relied on technical assistance to implement the TRIPS Agreement in accordance with Article 67, but others have included substantial incentives to promote technology transfer.

3.1.2. Under the CBD

The Convention on Biodiversity requires its members to co-operate internationally in implementing measures to conserve biological diversity. The industrialised countries in particular are called upon to support developing countries in implementing the Convention. Article 18 of the Convention formulates the goal of international cooperation and stipulates that priority must be attached to developing and strengthening national capabilities by means of human resources development and institution building. This capacity building at the national level is intended, among other things, to promote the development of national strategies to conserve biodiversity. Article 20 obligates the developed nations to provide new and additional financial resources for conserving biodiversity. Below are examples of the specific articles of the Convention to which assistance can be targeted:

- **Local knowledge and indigenous peoples (Art.8j).** The Convention on Biodiversity stresses the rights of indigenous peoples.

- **General measures for conservation and sustainable use of biodiversity (Art.6).** Measures with two different goals:
 - special strategies, plans and programmes aimed at conserving and sustainably utilising biodiversity; and
 - integration of the Convention's goals into sectoral and multi-sectoral plans, programs and policies.

The Convention also calls for independent national biodiversity strategies.

- **Identification and monitoring (Art.7).** CBD member states are obliged to identify ecosystems and habitats, species and biological communities, closely monitoring those components of biological diversity that possess the greatest potential for sustainable use.
- **In-situ conservation (Art.8).** In-situ conservation focuses on nature conservation, and includes the establishment and management of protected areas, plus support to indigenous and local communities.
- **Ex situ conservation (Art.9).** The principal function of ex-situ measures, to protect the various components of biological diversity outside their natural habitat, is to supplement in-situ protection. The methods used include zoos, botanical gardens, breeding stations, and gene banks. The goal is not simply to conserve the genetic information of these organisms but ultimately to permit their reintroduction into their original natural habitats.
- **Sustainable use of components of biological diversity (Art.10).** This is one of the cornerstones of the Convention. It requires development of policies that encourage utilisation of biodiversity to permit the survival of plant and animal species and cooperation between public and private sector.
- **Incentive measures (Art.11).** Both conservation and sustainable use is more likely if linked with economic and social incentives.
- **Research and training (Art.12).** CBD member states should establish (or continue) programmes for scientific and technical education and training devoted to the determination, conservation and sustainable use of biological diversity and its components. Appropriate research activities designed to help conserve and sustainably use biodiversity are to be specially promoted.
- **Public education and awareness (Art.13).** The Convention requires its members to promote awareness of how important it is to conserve biological diversity. This is to be achieved by dealing with these topics in the media and in educational programmes.
- **Impact assessment and minimising adverse impacts (Art.14).** CBD member states need to introduce procedures for environmental impact assessment of projects that might affect biological diversity, the means of taking such consequences into account, share information with other states, provide warning of any grave danger or damage that might affect them, develop national emergence responses and have appropriate contingency plans.
- **Access to genetic resources (Art.15).** Although CBD member states have sovereignty over their genetic resources, they should facilitate access by other members to these for environmentally sound uses. Accordingly, rules need to be drawn up to allow this and ensure that the original countries share appropriately in the resulting benefits resulting from their use.
- **Access to and transfer of technology (Art.16).** The member states pledge to grant other members access to technologies of significance for conserving and sustainably using biodiversity or to facilitate such access. This explicitly includes biotechnology and technologies for utilising genetic resources. Measures are needed to ensure the private sector is active in this and that members will cooperate to ensure IPRs are supportive of these objectives.
- **Exchange of information (Art.17).** A wide range of information exchange is needed with special focus on the needs of developing countries.

- **Technical and Scientific Cooperation (Art.18).** CBD member states shall promote international technical and scientific cooperation through national and international organisations and establish a clearing house to promote and facilitate this cooperation. For this national policies, capabilities, human resources development and institution building are needed, with special attention given to developing countries.

3.2. EU Commission technical and financial assistance

In addition to DG Trade, several Directorates of the Commission are in some way involved in policy related to either IPR and/or biodiversity issues and furthermore provide assistance to institutions and developing countries. The principal forms of assistance provided by two of these Directorates are detailed below (review of assistance by DG Environment will be provided in a future final version of this section).

3.2.1. DG Development

At present, DG development provides financial and technical assistance to developing countries under several cooperation programmes¹⁵⁴, including:

- co-financing of development projects undertaken by European NGOs in developing countries. The main aim of this policy of co-financing with NGOs is poverty alleviation through support for disadvantaged people in developing countries, to improve the qualities of their lives and reinforce their own development capacities;
- European Development Fund funding support. Assistance is provided for a wide range of sectors, and includes support for environmental protection, agriculture and tropical forest projects in developing countries;
- assistance to ACP countries via the Lome Convention, and assistance to Asia and Latin America (ALA).

Though significant funding is provided to developing countries under a wide range of programmes (some of which are agriculture, forestry and environment orientated), assistance is not provided in a way in which coherent action plans issues are targeted. Furthermore, in the case of the NGO co-financed and Lome programme, funding is provided to initiatives or requirements emanating from the developing countries themselves, each having their own development priorities. Hence, the EDF, NGO cofinanced or Lome programmes do not fund projects which specifically target implementation of the CBD or TRIPs (though some aspects may indirectly be supported under certain projects).

The DG Directorate is also responsible for funding the Commission contribution to the CGIAR. All member countries of the EU (with the exception of Greece) as well as the EU Commission contribute to the CGIAR and between them accounted for some 35% (\$120 million) of the 1998 CGIAR budget. The Commission in its own right has been the most significant contributor to the CGIAR since 1977 (with the exception of 1999 when no funds were contributed), and for example, in 1998 contributed in the region of \$25 million to the CGIAR. Commission funding to the CGIAR by the DG Directorate is due to resume in 2000.

3.2.2. DG Environment

At present DG Environment does not fund any projects in developing countries in this area and anyway project implementation would be handled by DG Development or External Relations. It has funded research related to its work. For example, along with the German Government, it funded a workshop on best practices in Access and Benefit Sharing in Cordoba and could consider funding further studies.

¹⁵⁴ Details of the Development Directorate's external cooperation programme are reviewed in 'the European Community External Cooperation Programmes, Policies, Management and Distribution. ODI, 1999'. This is available on the website: europa.eu.int/comm/scr/evaluation/odi-report/toc.htm.

The division is responsible for the negotiations in the CBD and is keen to ensure policy coherence within the Commission in developing positions on TRIPS and Biodiversity-Related Issues. It has worked with DG Trade and DG Internal Markets in developing the negotiating position for the Commission on the review of Article 27.3(b) in the TRIPS Council.

The directorate recognises that there is a policy tension between TRIPS and the CBD but no legal conflict. It is working to ensure that in their implementation they are mutually supportive and may commit its limited research funds to work on this. In the past it has funded work on biosafety and will probably focus on access and benefit sharing in the immediate future following the COP 5 decision to establish a negotiating group on access and benefit sharing. It will also take note of the work being done in WIPO and expects policy questions to be resolved in the CBD rather than the WTO.

3.2.3. DG Research

DG Research supports international cooperation with developing countries in the field of Research and Technology Development (RTD) under the INCO Framework Programme¹⁵⁵. These are joint research programmes bringing together EU and developing country institutions, the main aim being to help solve the problems faced in developing countries by increasing EU and developing country cooperation in research. Thematic areas of research funded under the RTD include Agriculture, Natural Resource and Health. Specific activities in the following areas are undertaken:

- Mechanisms and socio-economic and policy conditions for sustainable development: analysis of the factors facilitating the adoption of existing innovations.
- Sustainable management and use of natural resources: promotion of a sustainable relationship between population pressure, food security and the use and management of ecosystems; improvement of the productivity of renewable natural resources and prevention of their degradation.
- Analysis of the evolution in demand for agricultural products in these countries and research on ways of meeting this demand; improvement of the efficiency of agricultural production chains with particular reference to quality and health.
- Health improvement: research on equitable, efficient health systems and their impact; the influence of structural and policy aspects; coverage of vulnerable groups; quality of care and its acceptability and affordability; understanding of the major health problems in these countries and the development of instruments for prevention and control of the predominant diseases.

During the 4th RTD Framework Programme (1994-1998), 43% of INCO's resources were directed towards scientific and technological cooperation with developing countries in Asia, Sub-Saharan Africa, the Mediterranean and Latin America. 345 joint-research projects and 46 concerted actions were selected and funded, for a total cost of 196 MECU, of which roughly 50% was spent in funding partners in developing countries. These 391 consortia of scientists and research institutions, working in voluntarily established partnerships, involved around 2,400 scientific teams. Of these, half were located in developing countries and the remaining in the EU. The four year INCO 5 budget targeted for these purposes is some 210 million euros¹⁵⁶.

¹⁵⁵ Details of RTD cooperation and the INCO programme are detailed on the website: www.cordis.lu/inco2.

¹⁵⁶ Note that this funding level is small compared to the funding allocated by DG Research to the European Life Science Fund of 2.4 billion euros over the same period.

Importantly, however, though some issues relating to IP and biodiversity are covered by several research areas and projects under the RTD Framework Programme of INCO, there are no specific research areas and projects funded that explicitly tackle these issues.

3.3. Member State technical and financial assistance

Reviewed below are details of assistance provided by Germany, UK and Sweden, in the areas of TRIPs and biodiversity. The reviews are based on information and data provided by officials in the Member States. Also provided are details of Danish and Dutch assistance in the area of TRIPs only. We are awaiting information on Danish assistance to biodiversity in developing countries, and this will be incorporated when received.

3.3.1. German financial and technical assistance

3.3.1.1. German institutions providing assistance and areas of interest

Within the German Federal government, the Federal Ministry for Economic Cooperation and Development (BMZ) is responsible for planning and co-ordinating development cooperation activities and developing corresponding principles and programs. About one-third of German development aid funds flows into multilateral programs of international organisations such as the United Nations and its special organisations, the World Bank Group and the European Union. Some two-thirds of the budgetary funds managed by the BMZ go for bilateral projects and programs implemented with individual countries.

German development cooperation projects are conducted primarily through "Financial Cooperation" (FC) and "Technical Cooperation" (TC). Financial Cooperation funds are deployed by the *Kreditanstalt für Wiederaufbau* (KW) on commission by and in consultation with the German government. The task of FC is to provide investment capital to enhance partner countries' productive potential, including economic and social infrastructure, and/or optimise its utilisation. Technical Cooperation is devoted to raising the performance capacity of people and organisations in developing countries. The German government conducts TC activities through the *Deutsche Gesellschaft für Technische Zusammenarbeit* (GTZ) GmbH. TC concentrates on transferring technical, economic and organisational skills and supports measures to upgrade the preconditions for exercising these skills.

The *German Development Service* (DED) is a specialist national service providing human resources for Germany's Development Cooperation activities. The *Integrated Experts* Programme supports state and non-governmental organisations by providing human resources in addition to those experts assigned within the scope of technical cooperation. The *Centrum für internationale Migration und Entwicklung* (CIM), run jointly by the GTZ and the Federal Institute for Employment, arranges the employment of experts in developing countries and provides salary subsidies.

Projects on a trust basis (Funds in Trust, or FIT) are also conducted in cooperation between the German government and international organisations. In the field of biodiversity, conservation, a number of projects are being executed together with international organisations active in the fields of nature conservation and environmental protection.

Projects supported, countries targeted and funding levels

Germany now supports about 185 projects worldwide, through Financial and Technical Cooperation, , in which the conservation and sustainable use of biological diversity are the focus or at least a major sub-activity. A further 75 projects related to biodiversity are being promoted by allocating human resources. These are being implemented by DED and CIM. At present, projects with a total

commissioned value of DM 1.76 billion are being executed. Each year developing countries receive some DM 150-200 million through Technical and Financial Cooperation.

At the multilateral level, the Federal Republic of Germany makes a major contribution to the Global Environmental Facility (GEF), the most important pool of financial resources for conserving biodiversity. Between 1994-97, Germany allocated roughly DM 390 million to this facility, a large part of which is being used directly to conserve biodiversity.

50% of all ongoing Financial and Technical Cooperation projects are being implemented in Africa, 30% in Latin America, and 13% in Asia (see Figure 3.1). The rest is distributed between Europe and Russia. The breakdown of funding is similar: Of a total of DM 850 million, 50% is used for ongoing projects in Africa, followed by 32% or DM 550 million in Latin America, and 11% or DM 180 million in Asia. The rest is distributed between Europe and supraregional projects. This regional distribution is also reflected in the numbers of development workers assigned by the German Development Service (DED): whereas 72 persons are working directly to conserve biological diversity in Africa, there are 30 in Latin America and 20 in Asia. Thus, judged by the overall scope of Official Development Assistance (ODA), the activities to conserve biodiversity focus on Africa and Latin America.

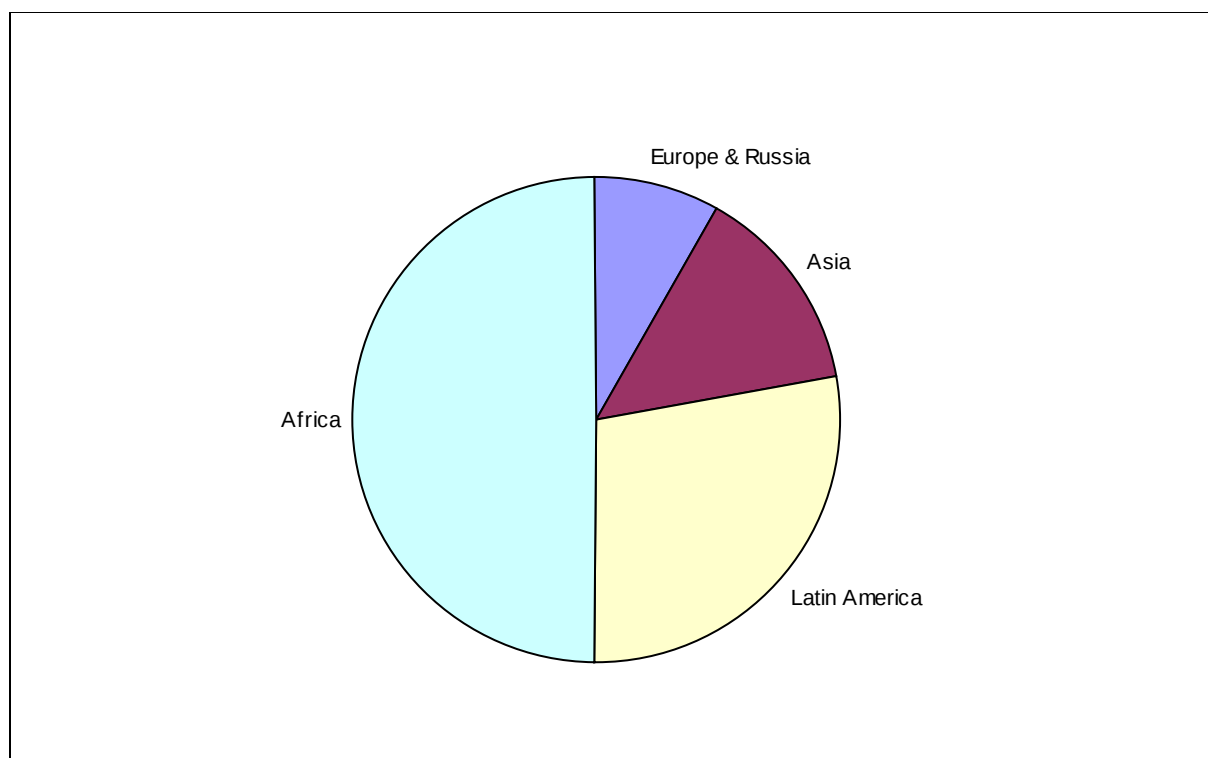


Figure 3.1: Regional distribution of financial and technical cooperation projects devoted to conserving biological diversity: funding

40% of the funds for conserving biodiversity in developing countries comes under Financial Cooperation. The breakdown of Technical Cooperation funds is 53% for Africa, 30% for Latin America, and 15% for Asia.

92% of the relevant projects of Germany's development cooperation for conservation of biological diversity are devoted to sustainably utilising components of biodiversity in accordance with Article 10

of the Convention (see Figure 3.2). 79% of ongoing projects attach priority to in-situ conservation (Article 8). 43% of the measures are devoted primarily to developing concepts, strategies and policies for conserving and sustainably using biological diversity (Article 6), and 38% of the projects to public education and awareness (Article 13). Other important goals pursued by the allocation of funds are research and training (Article 12: 24% of all ongoing projects), identification and monitoring (Article 7: 22% of all ongoing projects), and impact assessment and minimising adverse impacts (Article 14: 17% of all ongoing projects). Other high-priority goals of development cooperation projects are ex-situ conservation (Article 9), access to genetic resources (Article 15), access to and transfer of technology (Article 16), and exchange of information (Article 17), each accounting for less than 5% of the ongoing projects.

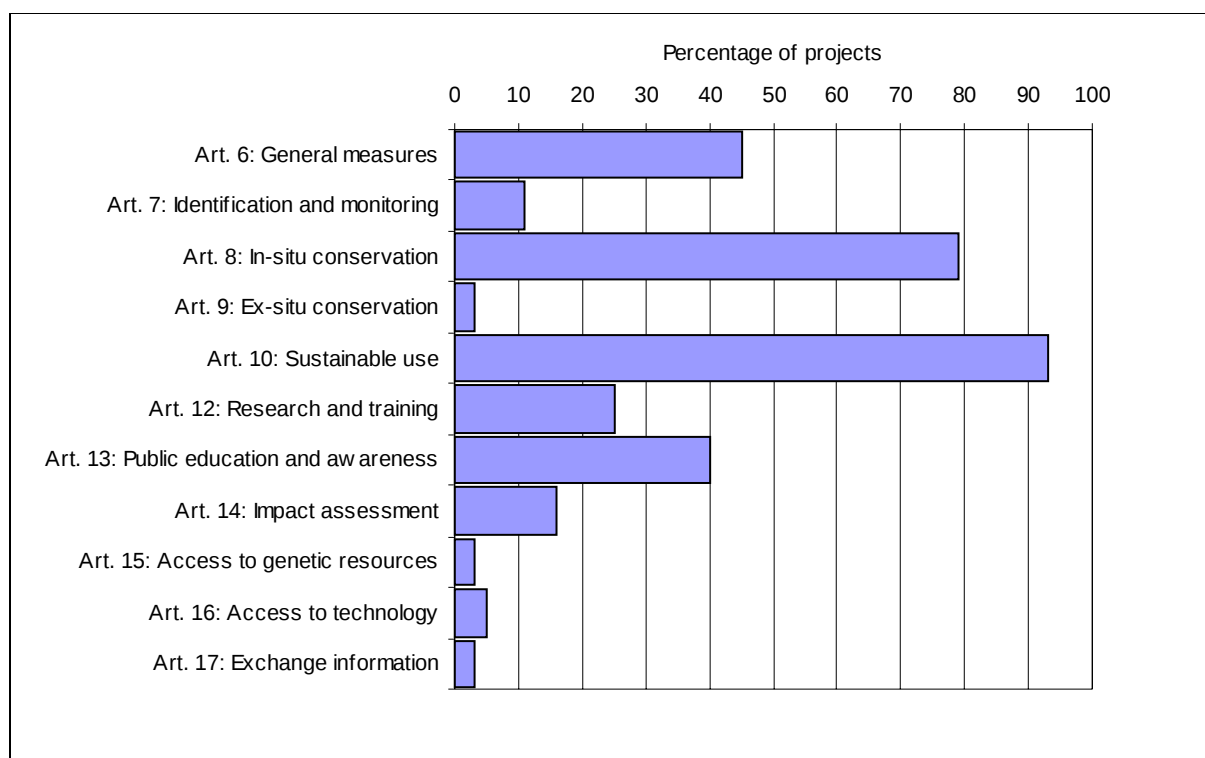


Figure 3.2: Implementation of the CBD through German financial and technical cooperation projects, showing the respective shares of the projects devoted to implementing the articles of the Convention.

3.3.1.2. Assistance provided for implementing the CBD

A central task of German development cooperation is to conserve biological diversity by developing appropriate instruments and implementing them through international cooperation. A large number of forestry, agriculture and nature conservation projects are already directly or indirectly addressing this. Below is an overview of ongoing Financial, Technical and Human Resources Cooperation projects, and of selected multilateral cooperation measures. Examples corresponding to the individual articles of the Convention illustrate how the CBD is being implemented with partner countries in Germany's cooperation for development.

Implementing the Biodiversity Convention (the BIODIV Project)

This BIODIV Project is being carried out by the GTZ on behalf of the BMZ. It is a sectoral project, in which selected institutions are being supported in member states. The emphasis is on projects having an innovative (pilot) character and model projects, and on measures geared to ward off direct threats to habitats or species. This project can also be designed to enable the partners to prepare for larger projects by working out their details and meeting the institutional prerequisites. In addition to large individual projects, supportive measures on a smaller scale are also promoted.

The tasks performed include the development of cooperation models intended to regulate access to genetic resources in developing countries. In an interministerial working group, concepts are elaborated for permitting utilisation of genetic resources that originated in developing countries while equitably distributing the profits deriving from this utilisation and using them to conserve biodiversity. Another task performed by the BIODIV Project is provision of support for implementing the *Clearing House Mechanism* the Convention calls for to promote international cooperation and information transfer in the field of biodiversity.

Examples of activities corresponding to specific articles of the CBD are:

Local knowledge and indigenous peoples

In a number of German development cooperation projects, an attempt is being made to protect the cultural identity of indigenous peoples and to strengthen their self-help potential. Thus in the project *Tropical Forest Protection in Gran Sumaco* (Ecuador), new sources of income are being created for the indigenous Indian population who live in the buffer zone of the Gran Sumaco-Galeras-National Park. The project *Demarcation of Indo Lands in Amazonia* (Brazil) attempts to make a contribution to the legal, physical and actual security of the property claims of Brazil's indigenous peoples. The local administration has been charged in the constitution with officially delimiting and demarking Indian lands but is not able to do so for lack of funds. The areas, which are unprotected due to a lack of national consensus, are subject to massive encroachment. The project aims to contribute to the creation of the prerequisites for demarcation and the ecologically sustainable development of these lands.

General measures for conservation and sustainable use of biodiversity

An example of a strategy development project supported by Germany is the "Programme for Conserving Biodiversity in *Namibia*". The first step in elaborating a national strategy is to survey the distribution and populations of selected plant and animal species and devise a programme to prevent the fragmentation of endangered populations. This then forms the basis for planning new protected areas and other measures to conserve biodiversity.

In *South Africa*, Germany is supporting the *Ministry of Land Affairs* in preparing concepts for a new nature conservation policy. At three locations, including the Krüger National Park, pilot models are being developed for reconciling the desire to protect nature reserves with the interest that local residents have in sharing in the development and utilisation of these locations.

In *Peru*, the national park service is receiving German support for elaboration of a strategy to secure already existing protected areas. The depressing general conditions there, combined with the weakness of state institutions and a lack of acceptance of protected areas by population groups living in them, prevent effective management from being practised; consequently, it is essential to come up with new concepts for elaborating alternative solutions, in many cases with the involvement of non-governmental organisations.

Identification and monitoring

Surveys and monitoring programmes play a major role in numerous Technical Cooperation projects. Particularly when planning protected areas, surveys of natural resources - capturing the actual situation - are frequently the starting point for all subsequent activities. The natural resources of habitats must be ascertained as the basis for deriving demarcation and zoning concepts. Within the scope of Technical Cooperation, wildlife censuses, vegetation surveys, and other types of biological inventories are a necessary prerequisite for protection programmes, although they are typically only sub-components of more comprehensive projects.

Since many developing countries are not able to conduct surveys and monitoring on their own, one of the goals of development cooperation is to improve the relevant institutional and human resources situation. In *Zimbabwe*, for example, the *Environment and Remote Sensing Institute* is being promoted through Technical Cooperation to establish an information system on vegetation resources. Use of this system is enabling, for the first time, nation-wide mapping of the current distribution of vegetation types, and monitoring of vegetative development and the status of vegetation. This is laying the foundation for the planning and management of sustainable utilisation of these resources at the national level.

In situ conservation

Examples of projects that involve protected areas include:

- Conservation of tropical forests in Gran Sumaco (Ecuador)
- Nature conservation and environmental protection in Turkey
- Integrated nature conservation in Mount Cameroon (Cameroon)
- Buffer zone development in Nyika National Park and the Vwaza Marsh Game Reserve (Malawi)
- Protection and management of Djoudi National Bird Park (Senegal)
- Nature conservation and buffer zone development (Mongolia)
- Buffer zone management (Bolivia)
- Rehabilitation of Murchison Falls National Park (Uganda)
- Promotion of Korup National Park (Cameroon)
- Protection, management and utilisation of biodiversity in the Paracas National Coastal Reserve (Peru).

Ex situ conservation

The projects supported here include support for the Biodiversity Institute (formerly: Gene Bank) in Addis Ababa (Ethiopia), where the establishment of a forestry gene bank and ex-situ populations to protect endangered tree and shrub species is being promoted, as well as measures to assign protected status to in-situ areas for high-priority species and forest ecosystems.

Because the genetic diversity of domesticated plants and animals and genetic modification of them also raises ownership issues, Germany is supporting a project devoted to investigating options for protecting varieties under the *TRIPS agreement*.

Sustainable use of components of biological diversity

These development cooperation projects extend both to sustainable use of individual plant and animal species, for example management of large game in Africa with controlled hunting or use of medicinal plants, and utilisation of various biological communities. Numerous forestry projects that emphasise

integrated, sustainable forest management. Some examples of projects devoted to sustainably using individual plants or animals are:

- Game management plan for the Kuku Group Ranch (Kenya)
- Community-oriented resource management (game protection) (Zimbabwe)
- Sustainable nature management in protected areas of Malawi
- Sustainable utilisation and preservation of endangered cycads and palms in Mexico
- Game management in Selous (Tanzania)
- Study of sustainable use of savanna areas (Ethiopia)
- Promotion of sustainable forest use (Kenya)
- Promotion of sustainable forest management in East Kalimantan (Indonesia)
- Promotion of sustainable forestry in Sarawak (Malaysia)

Research and training

The Tropical Ecology Support Programme (TOB) makes an important contribution to promoting research in biodiversity. Research into Applied Tropical Ecology is being conducted at the Visayas State College of Agriculture (VISCA). The institute's work has been promoted since 1988 through German development cooperation.

Basic and further training programmes are integral components of many development cooperation projects, particularly those engaged in institution building. Sustainability of the implemented measures can only be achieved by strengthening the situation of the institution executing the measures and enabling it to continue the measures on its own after completion of the project. Development of staff and institutional capabilities - 'capacity building' - forms part of virtually all development cooperation projects, being achieved through provision of advice, separate training components, and on-the-job training. Experts of the DED for example are active at the University of San Carlos in the Philippines to train local experts there in the fields of ecology, environment and biology, and at the Universidad Nacional de Ingeniería in Nicaragua they are helping to train local experts as environmental engineers specialised in applied ecology.

Public education and awareness

Although effective media work is often an essential prerequisite for successful project work, only a handful of development cooperation projects are devoted exclusively to this aspect. They include, for example, the establishment of a rain forest information centre in Sepilok near Sandakan, Malaysia (within the scope of a GTZ-financed measure), an environmental education programme that the WWF is conducting on behalf of the GTZ in Georgia, and a programme to raise environmental awareness in Southern Africa that the IUCN is carrying out on a trust basis under one of the German government's projects. In several cases, DED experts have also been commissioned to promote the process of environmental education and strengthening of environmental awareness. For instance, DED experts are advising the *Environmental Liaison Center International* in Kenya on training so-called eco-volunteers in the fields of environmental protection and resource conservation and the *Ministry of Education* in Mali on providing information and education to boost public awareness of environmental protection measures.

Impact assessment and minimising adverse impacts

The German government is promoting the further development of environmental impact assessment (EIA) in numerous development cooperation projects, through the sectoral project "Further Development of Environmental Impact Assessment Instruments", which aims both at improving the

technical competence of German development cooperation institutions and, in pilot measures, supporting developing countries in practising environmental impact assessment. For this, various regulations and administrative standards are compiled and analysed and the results placed at the disposal of interested parties in developing countries.

Access to genetic resources

Under the project "Implementing the Biodiversity Convention", an effort is being made to develop models for cooperation between the German pharmaceutical industry and developing countries. In addition, the *World Resources Institute* - within the scope of an FIT project conducted by the Federal Republic of Germany - is advising the governments of the Philippines and Indonesia on ways to regulate access to their genetic resources.

Access to and transfer of technology

Under German development cooperation, biotechnology procedures and methods are applied nearly exclusively in projects devoted to breeding of agricultural crops and promotion of gene banks. Projects and project components of this kind can also be found at international agricultural research centres, which guarantee transfer of the results to national institutions in the developing countries free of charge. Germany is supporting the work of the international gene banks in Ethiopia (Biodiversity Institute, Institute of Agricultural Research), Costa Rica (Centro Agronomico Tropical de Investigacion y Ensenanza - CATIE), and the national gene bank in Kenya (Kenya Agricultural Research Institute - KARI).

Exchange of information

Through the projects it supports, the German government is promoting the exchange of information that is needed to conserve and sustainably utilise biological diversity. In compliance with Art. 18 (3), Germany is also helping to set up a *Clearing House Mechanism (CHM)* to promote and facilitate the exchange of information within the scope of its project "Implementing the Biodiversity Convention". Support is given eg, to Cameroon and Colombia to establish their national nodes of the CHM, and to Kenya to make existing information bases available to the public through the CHM

The tropical ecology support programme (TÖB): Applied research to support ongoing development projects

The Tropical Ecology Support Programme is a supra-regional service project whose activities will help design development cooperation projects in a more ecologically sustainable manner. The programme promotes project backup studies on issues of relevance to tropical ecology. It is endeavouring to further develop concepts for the protection and sustainable utilisation of tropical ecosystems, which are to be the basis for innovative instruments for more environmentally compatible development cooperation. Four projects with similar objectives but different instruments, target groups and focuses are being co-ordinated under the umbrella of the TOB.

The areas of ecological research and tropical forest research are concentrating on applied research. Topics are worked out jointly by German and local scientists which facilitates further education of local experts and the establishment of expertise both in the partner countries and in Germany. TÖB has promoted approximately 140 short-term and long-term studies and about 65 small-scale projects in about 50 countries so far.

On behalf of the *German Federal Ministry for the Environment* (BMU), TÖB is also promoting small-scale projects carried out by local NGOs in close cooperation with German NGOs. This promotion is being funded from revenues of a "Special Stamp with Surcharge" sold in Germany.

The project "Protected Area Management" aims to support and distribute innovative strategies of NGOs in for protected areas. In cooperation with projects supported by German Development Organisations NGOs and other important actors are supported to take their responsibility for the management of protected areas.

Contributions to the CGIAR

The German contribution to the *CGIAR* is managed by the Federal Ministry for Economic Cooperation and Development (BMZ) and executed by the GTZ under the project "Promotion of International Agricultural Research". The GTZ provides technical advice to the BMZ for designing and implementing the overall programme, in addition to conduction research projects in consultation with the BMZ. This project is intended to help:

- alleviate poverty in developing countries through agricultural research;
- achieve food security;
- conserve natural resources.

The following efforts aim to achieve this goal:

- systematic support for international agricultural research centres;
- promotion of research work and programmes at the centres, whenever possible with the participation of German agro-scientists;
- strengthening of national agricultural research;
- improvement of cooperation among national, regional and international research institutions;
- utilisation of the knowledge and experience of German research institutes studying the tropics and subtropics to provide scientific advice to the German government, to encourage and intensify cooperation with national research institutions in developing countries;
- transfer of the results of international agricultural research to development cooperation.

Each project assistance activity is scheduled to run for three years. The GTZ assistance to individual projects involves total funding of about DM 23.5 million per year. 'Conservation of Agricultural Biodiversity' and 'Use of Phytogenetic Resources' are focuses of the German contribution to promoting the *CGIAR*. Table 3.1 indicates programmes and projects related to biodiversity presently being supported by Germany.

Table 3.1: CGIAR projects supported by Germany

Project title	Executing institution	Period/funding
Genotype and environment interaction in a core collection of tropical cover crops	Centro Internacional de Agricultura Tropical, Cali, Colombia (CIAT) with Hohenheim University	1995-1998 DM 402,000
Genetic improvement and management on multipurpose trees for agroforestry systems	International Centre for research in agroforestry, Nairobi, Kenya (ICRAF)	1996-1998 DM 2.3 million
Conservation and utilisation of plant genetic resources	International Livestock Research Institute, Nairobi, Kenya (ILRI)	1993-1996 DM 2.688 million
Spatial and temporal distribution of genetic diversity in wild forage species under stress conditions	International Plant Genetic Resources Institute, Rome, Italy (IPGRI) with the Free University (FU) of Berlin	1993-1997 DM 1.452 million
Morpho-physiological and genetic characterisation of traits for rice resistance to temperature stress	West African Rice Development Association (WARDA), Bouake, Cote d'Ivoire	1995-1997 DM 960,000
Fish biodiversity in the coastal zone: a case study on the genetic diversity, conservation and sustainable use of Tilapia in West African lagoons and watercourses	International Centre for Living Aquatic Resources Management (ICLARM), Philippines	1997-2000 DM 987,000
Enhancing diversity, quality and productivity of farmers' pearl millet genetic resources in Rajasthan, India	International Crop Research Institute for the semi-arid tropics (ICRISAT), Hyderabad, India	1997-2000 DM 667,000
Domestication of indigenous wild fruit trees of the Miombo woodlands of Southern Africa	International Centre for Research in Agroforestry (ICRAF), Nairobi, Kenya	1997-2000 DM 1,900,000
Contribution of home gardens to <i>in situ</i> conservation of plant genetic resources in farming systems	International Plant Genetic Resource Institute (IPGRI), Rome, Italy	1998-2001 DM 1,000,000
Strengthening the scientific basis of <i>in situ</i> conservation of agricultural biodiversity; Morocco country component	International Plant Genetic Resource Institute (IPGRI), Rome, Italy	1998-2001 DM 940,000

Source: Biodiversity conservation in German development cooperation

Integrated experts

Through development cooperation, the German government provides experts to take up positions of importance for development policy at institutions in developing countries. The *Integrated Experts Programme* supplements Technical Cooperation experts and experts assigned by non-governmental organisations. Integrated experts enter directly into an employment relationship with public or private sector organisations in a partner country, which pay them normal local salaries. These are then topped up by payments from German public funds. The placements and topping up payments are arranged by CIM, the Centrum für Internationale Migration und Entwicklung, a joint operation of the GTZ and the Federal Institute for Employment. At present, 26 integrated experts with tasks involving conservation of biodiversity are employed by partner-country organisations.

Germany's contributions to the global environmental facility (GEF)

Article 20 of the Convention on Biodiversity requires the developed countries to provide new and additional funds for conserving biodiversity. In addition to bilateral measures, cooperation within the scope of the Global Environmental Facility (GEF) constitutes the most important pool of financial resources for the conservation of biodiversity.

The GEF is a funding mechanism administered jointly by the UNDP and UNEP, to which developing countries, countries of central and eastern Europe, and the newly independent states have access. The funds cover additional costs incurred when measures taken by these countries address the interests of global environmental protection. The GEF disburses funds for investments and technical advice in the areas of climate protection, conservation of biological diversity, protection of international bodies of water, and protection of the earth's ozone layer. The GEF was established in 1991 in response to a German-French initiative, initially for a three-year pilot phase; subsequently, the

conventions (on climate and biodiversity) signed at the 1992 UNCED Conference in Rio de Janeiro identified it - initially on a provisional basis - as a funding mechanism for supporting the developing countries.

The existing instruments for bilateral and multilateral development cooperation can finance all measures that support implementation of the Convention on Biodiversity, particularly those that are in the interests of the respective country. The GEF, by contrast, limits itself to assuming additional costs incurred for measures that yield global benefits. During the GEF's pilot phase (1991 to 1993) a total of US\$ 1.13 billion was paid into it. The German government has played an active role in restructuring the GEF.

The binding contributions pledged by the donors for the time period from mid-1994 to mid-1997 total just over US\$ 2 billion. Germany is contributing US\$ 240 million (equivalent to about DM 390 million) of this, a share of 12%, ranking Germany as the third-largest donor after the USA (US\$ 430 million) and Japan (US\$ 414 million).

3.3.1.3. German assistance for biotechnology

The BMZ/GTZ Project "Development of Frame Conditions for the Utilisation of Biotechnology and Genetic Engineering" is being implemented by the Rural Development Division of the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH on behalf of the German Federal Ministry for Economic Co-operation and Development (BMZ).

This project is contributing to negotiations on:

- a legally binding biosafety protocol to assess and minimise risks in the transfer, handling and utilisation of living modified organisms as required by the Convention on Biological Diversity (CBD), Articles 19.3 and 8(g), which have been operative since 1993;
- the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and particularly to Article 27.3(b), which was one result of the GATT-Uruguay negotiations and constitutes part of the agreement creating the World Trade Organisation (WTO).

In developing countries, inappropriate framework conditions often make the utilisation of biotechnology in plant production problematical. Institutional control mechanisms for biosafety and for intellectual property rights (IPR) are not sufficiently developed in most of our partner countries. This situation increases the imbalance between industrialised and developing countries in developing, utilising, and commercialising innovations in the field of plant biotechnology. This project aims to help reduce international imbalances in developing, utilising and commercialising innovations in plant biotechnology by supporting partner countries in:

- elaborating *sui generis* systems for the protection of intellectual property rights that are geared to conditions in the respective partner countries;
- elaborating appropriate biosafety regulations.

Target groups

The project targets users of plant biotechnology for agricultural production (public and private plant breeders and seed producers), foods processors, and consumers. The project also focuses on political decision-makers both in developing countries and in Germany, providing a sound information

base for decision-making on policies related to biosafety and intellectual property rights in the field of plant biotechnology.

To foster awareness of these issues, the project also addresses the public at large through targeted public information campaigns carried out in close co-operation with both governmental and non-governmental organisations.

Activities

1. Identifying key players with experience in planning and implementing framework conditions that are geared to biosafety and IPR in developing countries.
2. Development of decision trees for the creation of biosafety regulations and IPR laws based on analysis of the conditions in partner countries.
3. Development of strategies to expand the transfer of knowledge about biosafety and IPRs.
4. Development of policies on biosafety and IPRs.

Services

1. Networking and fostering co-operation among key international and national players.
2. Development and implementation of appropriate concepts and strategies for the utilisation of plant biotechnology in development co-operation.
3. Support for national and regional workshops and training in the field of biosafety and/or intellectual property rights based on decision trees.
4. Advisory services to national and international policy-making bodies.

The Partners in co-operation include:

- Biosafety Research and Assessment of Technology Impacts of the Swiss Priority Programme Biotechnology (BATS), Basel
- Biotechnology Project of the International Centre for Agricultural Research in Dry Areas (ICARDA), Aleppo
- Biotechnology Research Institute / Scientific and Industrial Research and Development Centre (SIRDC), Harare
- Centre for Development Research (ZEF), Bonn
- German Foundation for International Development (DSE), Zschortau
- Intermediary Biotechnology Service (IBS) headquarters at the International Service for National Agricultural Research (ISNAR), Den Haag
- International Plant Genetic Resources Institute (IPGRI), Rome
- International Service for the Acquisition of Agri-Biotech Applications (ISAAA), Ithaca
- Scientific, Technical & Research Commission of the Organisation of African Unity (OAU / STRC), Lagos
- National (e.g., Forum on Environment & Development) and International NGOs and Networks (e.g., African Centre for Technology Studies (ACTS), Agriculture Peasant & Modernisation Network in Africa (APM), Mesoamerican Network of Plant Genetic Resources (REMERFI)).
- German Universities: Frankfurt, Freiburg, Hamburg, Hannover, and Hohenheim.

3.3.2. Technical and financial assistance provided by the UK

3.3.2.1. UK institutions providing assistance and areas of interest

Three UK governmental departments are involved with assistance on issues related to TRIPs and biodiversity:

- the UK Patent Office of the Department of Trade and Industry;
- the Department of Environment, Transport and Regions (DETR);
- the Department for International Development (DFID).

The assistance provided by these departments are detailed below.

3.3.2.2. Assistance provided for implementing TRIPs

The UK patent office, as part of the UK Department for Trade and Industry (DTI), is responsible for assistance under this agreement. The bilateral agreement with China remains the cornerstone of the United Kingdom Patent Office's technical cooperation activities. Table 3.2 summarises the main activities under this bilateral cooperation for the period 1998/99.

Table 3.2: Bilateral agreement with China

Date	Direction
7-13 June 1998	UK officials visited SIPO
2-5 November 1998	UK officials visited SIPO
24 May - 4 June 1999	Chinese officials visited UKPO
12-16 July 1999	Chinese officials visited UKPO

In addition, the UK Patent Office has hosted a number of visits from Intellectual Property Organisations from various countries around the world. The purpose of most visits from developing nations is to study the procedures and practices of the UK Patent Office in order to establish best practise to enable them to become compliant with the TRIPs agreement. Apart from China though, assistance to other countries is on an ad-hoc (ie, when they request it) basis.

3.3.2.3. Financial and technical assistance provided to biodiversity

Both the DETR and DFID are involved in assisting developing countries implement the CBD and improve biodiversity. The DETR takes the lead in negotiations on the CBD, and DFID works closely with them to ensure that developing country concerns are taken into account. DFID however has lead responsibility for the financial aspects of the CBD, under Articles 20 and 21, and with the exception of the clearing-house mechanism, for work under Article 18 relating to technical and scientific co-operation. The DETR provides biodiversity assistance to developing countries via the Darwin Initiative.

a) Technical and financial assistance provided by DFID

DFID is the British government department responsible for promoting development, the central focus of DFID policy is a commitment to the internationally agreed target to halve the proportion of people living in extreme poverty by 2015, and associated targets. The latter include sustainable development targets which aim to create sustainable livelihoods for poor people and protect the environment. To

help achieve these targets they work with multilateral institutions, and partner countries where DFID has programmes of bilateral aid.

DFID supports the CBD in two main ways:

- Funding development and research projects with specific biodiversity objectives;
- Integrating biodiversity concerns into other projects and programmes.

i. Bilateral initiatives

DFID's policy on biodiversity is to focus on the relationship between biodiversity and poor people. A number of DFID-funded bilateral projects include biodiversity concerns as a principal or significant goal. Three aspects are considered to be particularly important:

- the improvement of poor people's livelihoods through sustainable use and conservation of biodiversity;
- the protection of those livelihoods by preventing biodiversity loss - which can increase vulnerability and have disproportionate effects on the poor; and
- the provision of alternatives for people who would otherwise be forced to over-exploit biological resources.

DFID's bilateral projects concentrate on promoting benefits to the poor through an emphasis on capacity building (training people, sharing information and helping institutions to develop ways of meeting the challenge of managing their biodiversity) and coherence (linking local projects to national, regional and international policies, removing constraints and promoting incentives to encourage sustainability)

Over the past eight years DFID has committed:

- about £280 million to projects that focus on, or, contribute to DFID's policy objectives on biodiversity. Of this £170 million has been spent on projects that focus specifically on biodiversity and £70 million on capacity building/institutional strengthening;
- £147 million is currently committed to active biodiversity projects and £24 million committed to current capacity building/institutional strengthening projects;
- the assistance has targeted in the region of 200 projects since 1992 and over 40 countries.
- The prime focus of DFID's funding is on the poorest countries (LDCs), though projects in middle-income countries are supported too - where pockets of extreme poverty still exist and where environmental threats can have global consequences.

Developing country partners

DFID's work is done in partnership with developing countries - each of which sets its own priorities within the wider global context. In practice, DFID supports bilateral projects that:

- stimulate the sustainable use and management of resources, such as the Mount Cameroon Project - which, by involving villagers, the government and industry in the management of their forests, led to practical systems for sustainable harvesting of non-timber forest products;
- conserve genetic resources important to the future livelihoods of poor people, such as a project in East Africa which found ways for farmers to increase bean production by improving disease management - while maintaining the many local bean varieties;

- improve agriculture practices in a way that increases production and enhances biodiversity - like the INTERFISH project in Bangladesh, which introduced fish farming in rice fields and trains farmers in more environmentally friendly methods of pest control;
- promote benefit-sharing, for example by funding botanic gardens (in developing and developed countries) to collaborate in defining a common policy for the fair exchange of genetic resources;
- preserve the traditional knowledge that many communities hold about their environment, as is being done in Uganda, where the expertise of the Bahima pastoralists is defining new approaches to wildlife conservation in the Mburu National Park and is improving livelihoods.

Other partners

DFID has many other important partners:

- NGO partners. Many DFID projects involve non-governmental organisations. DFID provides matching funds for UK NGOs through the Joint Funding Scheme.
- Research partners. DFID funds a number of programmes of research undertaken both in the UK and overseas.
- Training partners.

ii. International initiatives

Internationally, DFID works with many organisations like the World Bank, the UNDP, and the FAO. It also seeks to influence international policy through UNCTAD and the WTO CTE. DFID also channels funds through international organisations with an environmental remit, principally the Global Environment Facility (GEF) and also the CGIAR centre ISNAR.

The GEF

The Global Environment Facility (GEF) is the financial mechanism for the CBD and other global environmental agreement. 165 nations (including the UK) participate in the GEF. Some 39% of all GEF projects relate to biodiversity. Since 1991 GEF has provided over \$775 million for nearly 250 biodiversity projects, and generated an additional \$1.2 billion in co-financing. To date, the UK has contributed approximately £225 million to the GEF. Some of that money supports GEF biodiversity projects, which for example are:

- working with Ethiopia's traditional farmers to preserve genetic material found in the seeds that they save and plant. This programme preserves globally important crop genetic resources for use by Ethiopian farmers and those in developed countries;
- working to establish a sound framework for effective management of Indonesia's coral reef systems - a major productive and aesthetic asset for the country's 67,000 coastal villages;
- helping to establish the Meso-American Biological Corridor from Mexico to Panama. The corridor covers more than 0.5% of the earth's dry land and includes protected areas that are home to 8% of the world's biodiversity. GEF is facilitating co-operation among nations to protect critical resources and provide economic benefit to local communities.

ISNAR

DFID is also supporting work in the International Service for National Agricultural Research (ISNAR) (one of the CGIAR centres), particularly under the following programmes:

- Globalisation of Agricultural Research. The programme aims to improve the capacity of the national agricultural research organisations (NAROs) in developing countries to adjust their

operations to the new conditions brought about by the globalisation process and make the necessary changes in the national research and development policy and programmes. The entire research programme will include a series of studies to evaluate the new roles of the NAROs in developing countries and put forward guidelines for determining their research agenda. These studies are:

- the role of the NAROs in alleviating poverty and maintaining food security;
 - possible forms of collaboration between the NAROs and the private sector;
 - the role of the NAROs in promoting agricultural research and development;
 - the impact of IPRs and the TRIPS agreement on the research strategy of the NAROs.
- Biotechnology, Biosafety and Intellectual Property Elements of the Information and New Technologies Programme.

b) The DETR Darwin Initiative

The UK Department of the Environment, Transport and the Regions (DETR) has responsibility for UK dealings on all international environmental agreements and conventions.

The Darwin Initiative for the Survival of Species was announced at the Earth Summit in Rio in 1992 and is now in its eighth year of funding. It helps developing countries implement the Convention on Biological Diversity, signed at Rio, through collaborative partnerships and with British expertise. The DETR administers the Darwin Initiative and operates as a rolling grant programme, with a budget of £3m per annum. Each year, between 25 and 35 grants are awarded to British universities and other British scientific or research establishments which establish collaborative biodiversity projects with developing countries to assist countries to meet their obligations under the Biodiversity Convention.

By 1999 the Darwin initiative had committed £21 million to almost 200 projects with links to over 80 developing countries around the world. A typical Darwin project involves a UK biodiversity institution receiving about £40,000 to £45,000 a year for three years to carry out research and/or training in collaboration with a partner in a developing country.

A list of new projects is given in Table 3.3 below. Well over 200 projects taking place in over 80 countries have been funded since 1993. Some key project areas are:

1. building institutional capacity
2. training
3. research
4. work to implement the Biodiversity Convention of 1992
5. environmental education or awareness

Each year £3 million is allocated to about 25 projects, which can run for up to three years. An advisory committee of experienced people from a range of biodiversity related fields advises Ministers on which applications to accept. Here are some of the Darwin Initiative's key guidelines:

- the Darwin initiative will assist countries rich in biodiversity but poor in financial resources (including Overseas Territories of the United Kingdom) with the conservation and use of biodiversity and implementation of the Biodiversity Convention;
- these countries will be those where work on conservation and the use of biodiversity would not be carried out without such funding. Funding will raise awareness of potential worth and sustainable use of natural resources to help eliminate poverty in those countries;

- projects will have a real and lasting impact on the capacity of the recipient country to meet its obligations under the Biodiversity Convention.

Technical assistance projects are by far the most common projects to have received funding. The trend in funding this type of project has changed over time from being predominantly concerned with projects which improve the information base on particular habitats species, to more applied work on providing information relevant to the preparation and implementation of conservation/management initiatives (see Figure 3.3).

To March 1998, the Initiative had provided grant funding in excess of £18 million to assist developing countries to meet their obligations under the Biodiversity Convention.

Africa has been the target region for the largest proportion of projects: 30% of projects to date have specifically targeted one or a number of African countries (see Figure 3.4). South East Asia is the second most popular region targeted by the Darwin Initiative, with 16% of projects. Approximately 7% of projects have operated in more than one region, the majority of which are training projects that involved training individuals from a number of countries.

Table 3.3: List of successful projects under the Darwin initiative

Institution	Description of project	Country	Total (£K)
Bermuda Zoological Society	Development of a Biodiversity Strategy and Action Plan	Bermuda	99
Cardiff University	Conservation of the orang-utan in Kinabatangan Wildlife Sanctuary, Sabah	Malaysia	147
Centre for the Economics and Management of Aquatic Resources, University of Portsmouth	Effective management for biodiversity conservation in coastal wetlands	Sri Lanka	146
Community Environmental Educational Developments	Give a Hand to Nature – Biodiversity training and capacity building	Poland	69
Environmental Change Unit,- University of Oxford	Sustainable development of biologically unique littoral forests	Madagascar	79
Fauna & Flora International	Renewing management of Sapo National Park and creation of the Liberian protected areas system	Liberia	93
Field Studies Council	Schools and Communities Monitoring and Protecting Biodiversity	Slovakia	129
Imperial College of Science, Technology and Medicine	Conservation of the Paguyaman forest in North Sulawesi	Indonesia	190
Institute of Zoology	Development of a research and monitoring unit at Garamba	Democratic Republic of Congo	132
National Museums & Galleries of Wales	Terrestrial Invertebrate biodiversity in Galapagos: Training and collection rehabilitation	Ecuador	161
Raleigh International with Macaulay Land Use Research Institute	Large mammal conservation and sustainable resource use in Khan Khentii Special Protected Area	Mongolia	152
Raleigh International with UK Forest Research Agency	Huemel ecology research for conservation planning	Chile	133
Royal Botanic Garden Edinburgh	Tree diversity and agroforestry development in the Peruvian Amazon	Peru	142
The Natural History Museum	Tools for monitoring soil biodiversity in the A.S.E.A.N. Region	Malaysia	101
The Royal Geographical Society (with The Institute of British Geographers)	Plankton biodiversity: training, sampling, taxonomy and data-evaluation	Seychelles & Mauritius	142
University of Oxford	Big cat conservation and sustainable management in Southern Africa	Southern Africa	154
University of Oxford	Framework for monitoring invasive tree species	Ghana	87
University of Reading	Conservation of the endangered jerdon's courser	India	70
University of Strathclyde	Conservation and rehabilitation of the rainforest by indigenous people	Colombia	175
University of York	Conservation of whale sharks and fish spawning aggregations	Belize	129

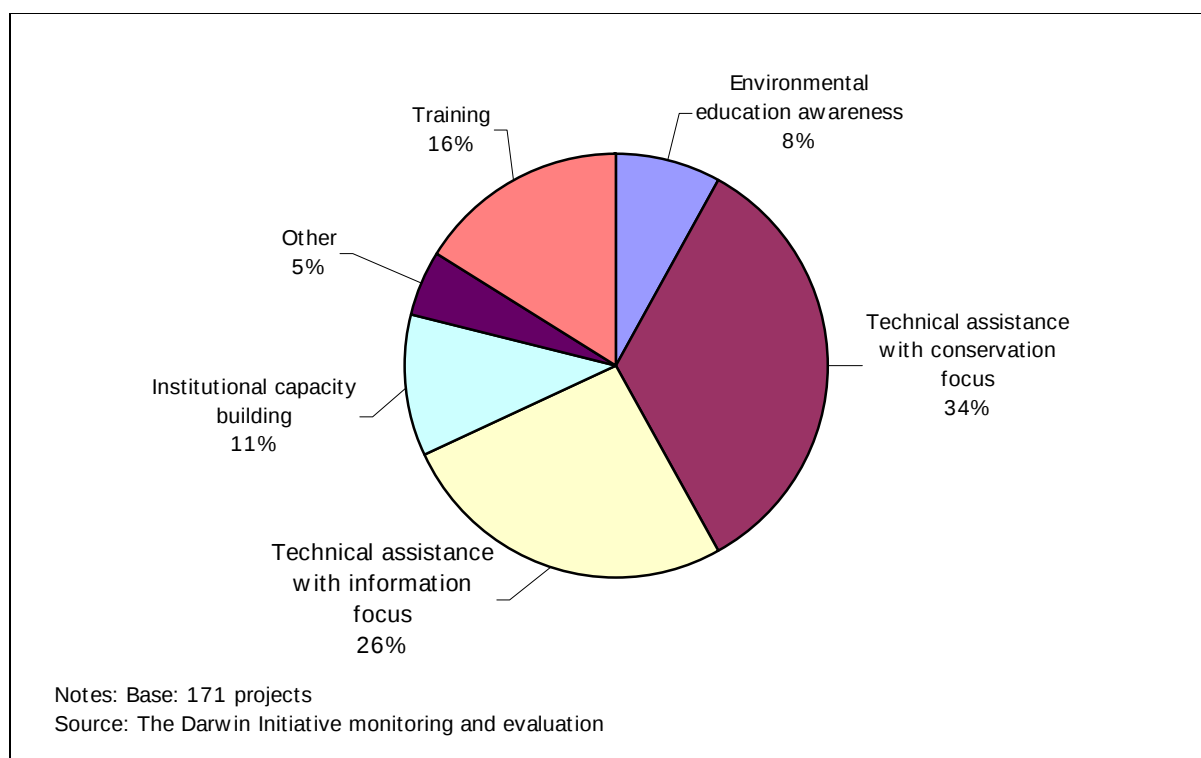


Figure 3.3: Analysis of project type by number of projects

The projects have varied immensely. Some, such as the World Wide Fund for Nature at Jordanhill in Glasgow and the University of Birmingham have run training courses using their facilities in the UK and bringing students from many different countries. Others have concentrated on research in the host countries. Plymouth Marine Laboratory carried out a project in Thailand looking at the gene flow and genetic diversity of cultured native oysters to identify resource management procedures to help restore the efficiency of oyster production.

It has also been an integral part of the Initiative to have projects that directly involve local people and take their views and needs into account. The University of Oxford worked in the Philippines to help local fishermen safeguard their stocks of seahorses and devise a method of using them sustainably. The Zoological Society of London has been working with partners in Ethiopia to identify a new conservation area in the Central Highlands.

While all projects provide the host country with much needed information and expertise to help them meet their obligations under the Biodiversity Convention, some projects address directly issues in the Convention, such as intellectual property rights and benefit sharing. The Foundation for International Environmental Law and Development has carried out training for environmental lawyers from developing countries. It enabled them to meet to discuss implementation of the Convention and bring together the particular experiences of developing countries' problems and needs. The University of Strathclyde has also used Darwin funding in their work in Africa to help government officials formulate and implement public policy in relationship to environmental issues.

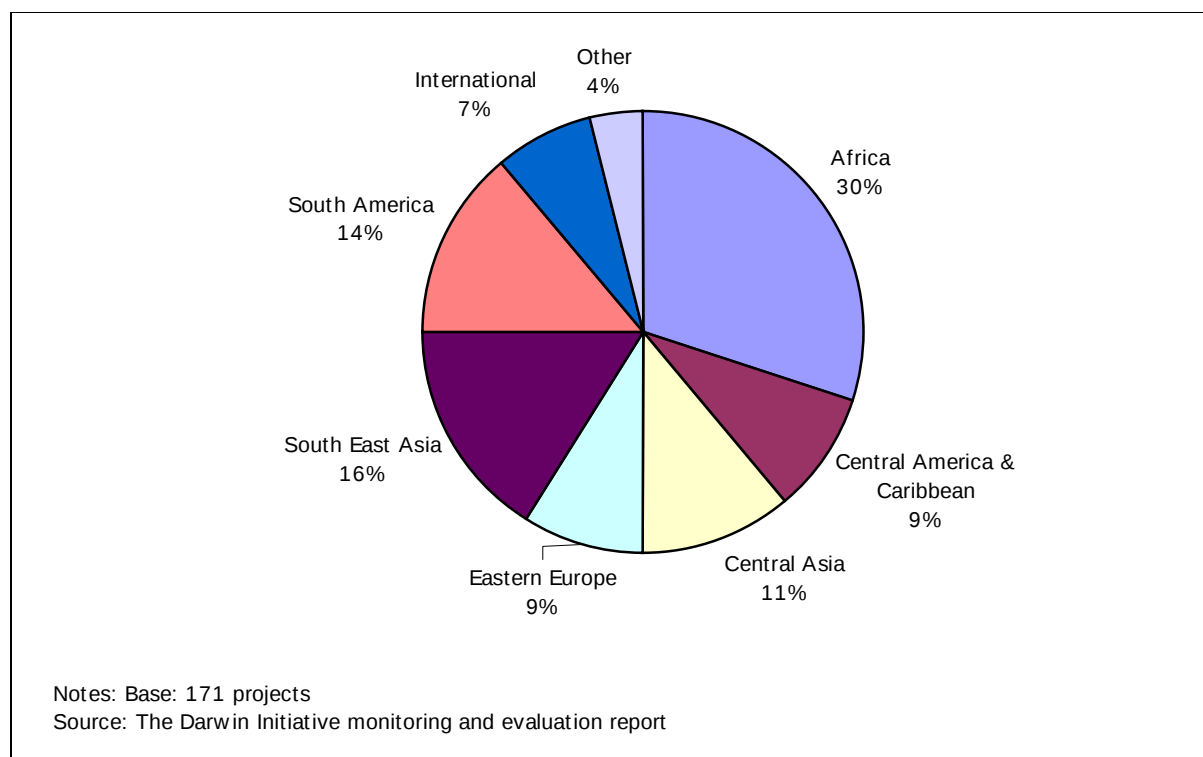


Figure 3.4: Geographical coverage of projects funded by the Darwin Initiative: analysis of number of projects

3.3.3. Swedish technical and financial assistance

3.3.3.1. Swedish institutions providing assistance and areas of interest

Institutions involved are the Swedish Patent Office and the Swedish International Development Cooperation Agency (SIDA). Swedish officials believe that Sweden provides a broad and rather informed involvement in CBD and TRIPS related issues, and it is felt that this constitutes coherent analysis and constructive contributions by Sweden to the international policy process on genetic resources and IPR.

3.3.3.2. Assistance provided for implementing TRIPs

Funding to WIPO and support by the Swedish Patent Office to Developing Countries involved in WTO Round Table/Integrated Framework. These countries may request support on CBD and TRIPs issues from the WIPO and the Swedish Patent Office.

3.3.3.3. Assistance provided to biodiversity

A wide range of activities/programme/projects are presently supported by SIDA. Examples of the principle ones are:

1. *Contribution to the CGIAR.* 10 million Euros a year is provided to fund CGIAR activities and those of its network of 16 agricultural research centres. Several of these deal explicitly with CBD and WTO (TRIPs) issues, such as the IPGRI, IFPRI, and ISNAR (in particular its IPR advisory unit).
2. *African Centre for Technology Studies, ACTS.* This project is based in Nairobi and provides advice to African countries on biopoly and TRIPs/CBD policy issues.

4. *Linnaeus Initiative*. This initiative aims to strength taxonomic capacity in developing countries, through training courses, seminars, exchanges etc.
5. *Crucible II project*. This is a science & policy forum implemented in 1994, providing a base for discussions, papers and seminars on policy annotated legislation for the protection of biological innovation and trade, knowledge and access to genetic resources, in light of the TRIPS agreement.
6. *Harmonisation of national policies for the management of genetic resources*. Eight case studies (four of developing countries and four of OECD countries) related to an analysis of why there is a stalemate in the FAO's IU initiative and a partial breakdown in the FAO Commission of genetic resources.
7. *Bioearn programme*. This provides support to four East African countries to strengthen national capacity in biotechnology and biopolicy. The principal issues include and exchange of genetic material and technology in a proprietary context.
8. *SADC (Southern Africa) genebank*. Support for the development of a physical infrastructure, and the provision of technical training. A similar programme is in progress in East Africa.
9. *Community based biodiversity conservation/utilisation* with case studies in Africa and Asia. Test projects are been undertaken that examine the ways and means to implement *in situ* conservation and utilisation.
10. *Support to a wide range of NGOs*, such as GRAIN and TWN, on advocacy work.
11. *Ad hoc support to the FAO IUPGR facilitation process*. This involves support for informal consultations with key stakeholders to facilitate the formal negotiation process.
12. *Awareness building initiatives both in Developing and OECD countries*. The awareness building initiatives include seminars and publications, which focus on advising governments that they have commitments and obligations under a wide range of institutions (UNCTAD, WTO, CBD, FAO, UPOV, WIPO, ILO, UNESCO), and hence the need for coherence in national positions and international negotiating foras.

3.3.4. Danish technical and financial assistance

3.3.4.1. Assistance provided for implementing TRIPs

The Danish Patent and Trademark Office (DPTO) has not participated in technical and financial co-operation as mentioned in the TRIPs-agreement article 67 and 66.2 nor have they participated in initiatives regarding the IPR's and biodiversity.

For many years the DPTO has carried out courses arranged in connection with the WIPO "training programme for officials from developing countries working in the field of industrial property". These courses consist of practical training provided for representatives of developing countries. During the 14-day courses participants are - among several other subjects - also provided information about the TRIPs-agreement and the Danish implementation thereof.

The DPTO provides the knowledge of relevant experts and conducts the transfer of knowledge during the study visits. The WIPO pays for travel and accommodation. The DPTO aims to host such seminars every second year.

The DPTO funds the Danish contribution to WIPO. The annual contribution amounts to 1.9 Million DKK (about 250,000 euros).

3.3.5. Technical and financial assistance provided by the Netherlands

3.3.5.1. Assistance provided for implementing TRIPs

A. The Netherlands Industrial Property Office (NIPO). NIPO is responsible for training assistance to developing countries on IPRs. NIPO contributes to the technical assistance by means of training, seminars and exchanges and collaborates in this field with the European Patent Office, Directorate 5.2.3. The principal areas of assistance supported by NIPO are:

- WIPO: Training course on patent examination for participants from Asia, Africa and Latin America.
- AIPT: Administrative Issues on Patents and Trademark Procedures. Seminar on administrative issues of the patent and trademark procedure for participants from Asia, Africa, Latin America and East Europe.
- Regular exchange of patent literature with several countries from Asia, Africa and East Europe.
- Receiving foreign delegations.
- Under the framework of WIPO's Industrial Property Programme for developing countries, the Benelux Trademarks Office (of which NIPO is part) organises every year a specialised training course on the administrative and legal aspects of trademarks for some 20 participants from developing countries.

B. Plant Research International. Plant Research International is responsible for research on (new) plant varieties (covered by Part IIL Article 27.3(b) of the TRIPS agreement). Assistance takes the form of international courses in the area of the protection of plant varieties: legislative support, institutional and botanical/technical support. Examples of recent assistance include:

- Indonesia: 1 week course advising the Agency for Agricultural Research and Development (AARD). There will be a follow-up in 2000 on further advise on institutional and technical execution of the protection of plant varieties.
- Philippines: 3 days participation in a workshop on legal-and institutional questions, for the PCCARD (a research organisation).
- China: 1 week advising the Ministry of Forestry on how to carry out research on the protection of plant varieties for trees and plants. For 6 months a person from the Chinese Ministry of Forestry undertook a course in the Netherlands.

3.4. Conclusions

Implementation of TRIPs and the CBD by developing and in particular least developed countries must be underpinned by continuous access to know-how and environmentally safe technologies, and access to resources for capacity building and institutional development. These requirements are acknowledged under obligations in TRIPs (Article 67) and the CBD (Articles 18 and 20), and are seen as important by both industry and NGOs (see Section A of the study).

The description of assistance in this section clearly shows that the EU Commission together with the individual member countries Many European countries do provide significant levels of support to developing countries in their efforts to build stronger and better functioning national Institutions and services, and enhance their implementation of policy. However, the review of assistance in this Section clearly shows that:

- assistance targeted specifically to issues covering TRIPS and biodiversity as it relates to IP are limited;
- a wide spectrum of policies, priorities and preferences exists today among EU countries and the EU Commission with regard to assistance in the areas of TRIPS and biodiversity;
- the IU and agricultural biodiversity appears to be poorly integrated into the mix of assistance provided. Although it may receive support, it was not specifically identified by our respondents except by the Swedes.
- there are many actors involved in the EU at the Commission and national level, and at the policy and at the institutional levels in donor and developing countries and international organisations, all with their own priorities and strategies. Hence different Directorates of the Commission and Member States prioritise areas of assistance and select areas to be funded based on policy dialogues and cooperation with groups of countries and regions concerning their needs, priorities and specific socio-economic requirements, taking also into account their development policy objectives and internationally agreed development targets, as well as past experience gained. However, this may not produce a coherent strategy that understands the linkages between these and the role activities in the different areas play in the changing market structure.

EU policy makers should therefore be aware of measures that would assist in creating an improved assistance environment, such as the following:

- better coordination to enhance complementarity, synergy and cost effectiveness. This includes the need to strengthen and maintain long-term commitments to institutional development in IP and its role in different environments and economic circumstances, and sharing experiences of institution strengthening and mechanisms for partnerships with developing countries;
- more targeted funding to meet specific requirements. Article 67 of the TRIPS Agreement obliges developed countries to provide technical cooperation on request and on mutually agreed terms and conditions in favour of developing and least-developed country Members including in the preparation of laws for the protection of IPRs and the prevention of their abuse. Similarly, MEAs often include financial mechanisms such as the Global Environmental Facility (GEF) under the CBD and the Financial Mechanism under the *Convention on Desertification*¹⁵⁷ that could be

¹⁵⁷ The *United Nations Convention to Combat Desertification in Those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa* includes a financial mechanism under Article 21. The Convention includes substantial references to the protection of indigenous and local community knowledge and the sharing of benefits from its use – see Articles 16, 17 and 18.

sources of funds for implementation and amendment of IP systems that accommodate the environmental objectives of MEAs.

- communication between Directorates, between member states and member state departments and between EU Directorates and member states. As negotiations over IPRs and biodiversity touch not only on intellectual property and environmental issues, but on food/agricultural, health, trade and technological issues, a coordinated policy nationally is important to ensure that a coherent position is advanced across all international negotiations – in the TRIPS Council, at the FAO, the CBD and WIPO.
- review the possibility of undertaking empirical research into this issue as part of their work programmes, and should encourage surveys and research into the role of IPRs on national development. In Section B of the report it was argued that a significant drawback in determining the role of IPRs in protecting the environment, encouraging technology transfer, creating incentives for research, promoting global health and so on, is the lack of empirical research upon which to base sound conclusions. The results of such research will help provide the basis for effective implementation of existing international obligations as well as the basis for future negotiations in this area.

SECTION D

4. Assessment

This final section makes suggestions we believe will support the Commission's objectives in relation to TRIPS and biodiversity-related issues and it outlines priorities to be considered by the Commission. Our recommendations include:

- those designed to enhance the functioning of policy making in this area in the Commission; and
- specific suggestions related to issues brought out in the earlier sections of the report dealing with implementation issues.

4.1. EC objectives

On the basis of interviews done and information received we find the Commission's objectives in relation to the TRIPS Agreement and Biodiversity related-issues should operate to:

1. Allow the Commission and member states to balance their TRIPS and biodiversity objectives within the broad range of national and EU interests, as, for example, outlined at the Lisbon summit in March 2000, at which member states agreed to aim to become the most competitive and dynamic knowledge-based economy in the world.
2. Enable both member states and the Commission to achieve policy coherence in this area. For the Trade and other Commission Directorates, the aim is to ensure that TRIPS, the CBD and other international instruments, such as the IU, are interpreted and developed in a mutually supportive way.

4.2. EC internal policy making

Our research suggests that the Commission's capacity to develop policy in this complex area with implications for many sectors could be improved through a greater involvement of a wide range of interests in the Commission. Interviewed parties have suggested that the development of IPRs in general has suffered from lack of involvement of a wide range of stakeholders, although this is now changing as the implications of the TRIPS regime set in. Moreover, some interested parties suggest that there is no clear picture of the work going on in the Commission and Member States to address concerns raised by developing countries and civil society organisations regarding the relationships between TRIPS and Biodiversity-related issues.

Thus we suggest the Commission:

- arranges for a complete survey of technical and financial assistance (building on the sample survey in section C of this report) being provided in this area as a useful baseline for developing coherent policy in this activity. This should be published;
- follows-up this study by publishing it widely so that the various stakeholders may make use of it; and,
- holds an external workshop involving relevant ministries and stakeholders from member states and international institutions regarding co-operation to develop greater dialogue about policies in this area.

4.3. Recommendations for action

4.3.1. On implementation issues

A range of possible actions emerge from the earlier discussion in the report that would develop work in this area.

As suggested by several parties, a review of TRIPS could be developed with special emphasis on the perspective of developing countries who are arguing, in effect, that TRIPS favours large country, high technology economies. Since, as has been shown, certain stakeholders find that the distributional and development implications of TRIPS create concerns, the Commission should seek to establish a dialogue to examine these allegations further. More specific recommendations include:

- A. The Commission should support work on parts of TRIPS that could provide solid gains for developing countries - for example, proposals from developing countries to expand the scope of TRIPS Article 23 so that additional protection for geographical indications may be available for goods other than wines and spirits (B2.1.2.3(f)).
- B. The EC should take a constructive approach to the arguments of developing countries that they are unable to implement TRIPS within the present time frames set by the agreement.¹⁵⁸
- C. The EC should also take a constructive approach to those parts of TRIPS that allow WTO members to exclude inventions from patentability, for example where specific plants and animals are sacred for particular groups, or to protect animal and plant life or to avoid serious prejudice to the environment. The purpose of these provisions is, after all, to allow room for the sovereign expression of deeply held cultural values. The EC should, for example, study how jurisdictions with different socio-economic conditions implement article 27.3(b) of TRIPS. (B2.2.1 and 2.2.2).
- D. The EC should study the usefulness of including mandatory requirements for disclosure of the origin of genetic resources and of traditional knowledge used in inventions for which IPRs are claimed, the country and community of origin of these resources and knowledge, and proof of consent having been sought of the relevant community and equitable benefit-sharing arrangements having been entered into with them, as required by the CBD. The implications of each of these for other stakeholders, eg, SMEs, and risks, eg, that greater recourse would be made to non-disclosure (trade secrets) routes to protecting innovation rather than patenting also need to be considered. The Commission should not require agreement on all of these areas to impede agreement on some, for example, on declaration of geographic origins and use of traditional knowledge which require at most further clarification of information that many applicants provide anyway. Indeed, Novo Nordisk has made a public undertaking to mention the country of origin in its patent applications (B2.1.2.4).
- E. The EC should ensure financial and technical assistance is provided to developing countries to:
 - develop *sui generis* systems for Plant Variety Protection in close co-operation with national governments based on specific national requirements.
 - strengthen their ability to implement the CBD and develop effective legislation with enforcement mechanisms as a complement to assistance to implement TRIPS.

¹⁵⁸ We note that in the WTO context generally Pascal Lamy has pointed out that the EU advocates a constructive response to the implementation concerns of developing countries. See Pascal Lamy, 'The link between Trade and Development – What role for the EU Trade Policy, Speech, AIF Conference, Christianborg, 12 September 2000.

- F. The EC should assess the role that a global bio-collecting society representing the interests of indigenous people could play in the protection of indigenous knowledge in conformity with Article 8(j) of the CBD (B2.2.2.1 and Appendix 3).
- G. The EC should also:
- ensure regulations concerning databases dealing with genetic resources do not impede access to knowledge and scientific exchanges necessary for maintaining and safeguarding biodiversity (B 2.1.2.3(b)) ;
 - develop ecological analyses of impact that internalise environmental, social and cultural costs and ensure equitable allocation of liability for and adverse consequences of innovation on biodiversity.(B2.2.4).

4.3.2. On more fundamental questions

TRIPS is an international instrument that was born out of many specific interests.¹⁵⁹ Today there are a wide range of people who question its moral, political and economic legitimacy(A1.3). Since its negotiation, some developing countries have expressed the view that they consider the agreement unbalanced due to a series of concerns. A failure to address these concerns about TRIPS, we predict, will generate instability for the entire WTO trade liberalisation regime. In this context, we note Pascal Lamy's recent observation that the "institutions of global governance, including the WTO, are not popular".¹⁶⁰ TRIPS, we suggest, is increasingly a source of that unpopularity.

It has been argued that TRIPS creates a threat by supporting unchecked private global power over the world's biodiversity. Many citizens groups fear that patent-driven R&D in biological materials may transform their social, environmental and moral worlds in unimaginable ways(B2.2.2) Many industries, however, are concerned that these fears will undermine their capacity to develop new products and services in a liberalised global market to the detriment of economic development in the EU and the world(A1.2). TRIPS is increasingly becoming the target of international NGO activity. It is clear to us that TRIPS and the processes that lie behind it must become the subject of greater transparency and debate. This requires more transparent processes in the WTO, greater interaction between the agencies concerned and broader involvement of the whole range of stake-holders in developing future work in this complex area. We suggest therefore that consideration be given to the following:

Broader inclusive decision-making

The European Commission should consider establishing multiple regulatory linkages between different sectors so that regulators are able to deliver high quality analyses and policies on TRIPS and biodiversity-related issues. At the same time it should also seek to strengthen input from developing countries, NGOs and broader civil society. Within the WTO framework it should support both the CBD and FAO having observer status on the TRIPS Council, and moves to increase the transparency of WTO processes.

Balancing a broader range of interests

The tensions between intellectual property rights and competition are well known. In the USA, for example, the Chairman of the Federal Trade Commission has questioned US Federal Court patent

¹⁵⁹ For the history see P. Drahos, 'Global Property Rights in Information: The Story of TRIPS at the GATT', 13 (1995) *Prometheus*, 6.

¹⁶⁰ Pascal Lamy, 'Do Developing Countries Have Their Rightful Place in WTO Priorities?', Speech, World Economic Forum, Southern Africa Economic Summit, Durban, South Africa, 22 June 2000.

decisions that appear to ignore the anti-competitive potential of patent rights¹⁶¹. The potential for anti-competitive conduct is of considerable concern to those working in the food and agriculture field owing to the continuing consolidation of the industries dealing with biological materials and the use of IPR protected processes and products in R&D in this field and the effects this may have on biodiversity (B2.2.3.2). The EC should:

1. Begin, in co-operation with national competition authorities in Europe and elsewhere, a special programme of monitoring the patterns of proprietary control of fundamental biotech research tools and structural and functional genomic data and assess the impact of these on:
 - market structure and power in the agricultural, food and other markets that may affect biodiversity;
 - research priorities and the direction of R&D;
 - the practices of firms in the licensing of intellectual property related to biological processes and materials
 - effects on public welfare (section B 2.2.3.2 & 3).2
2. The EC should provide assistance to enable developing countries to exchange experiences on access and benefit sharing legislation with each other as well as technical assistance in developing such legislation. Some countries have already introduced such regulations and explaining their experiences in developing and implementing them would be helpful for other countries that are in the process of doing so. The EC should also consider ways to support access and benefit sharing regulations in other countries by introducing complementary user measures within the EU as COP 5 urged countries receiving genetic resources to do through Paragraph 4 (c) of Decision 26 ("Access to Genetic Resources").

Action on this range of recommendations will help ensure the implementation and development of these two legal instruments, TRIPS and the CBD, along with the emerging International Undertaking, in ways that are mutually supportive of the broader development goals espoused within each of them.

¹⁶¹ Robert Pitofsky, Chairman Federal Trade Commission, 'Challenges of the New Economy: Issues at the Intersection of Antitrust and Intellectual Property', American Antitrust Institute, National Press Club, Washington DC, June 15, 2000. Available at <http://www.ftc.gov/speeches>.

Appendix 1: List of stakeholders and organisations consulted

International Organisations and forums

- CBD: Hamdallah Zedan, Executive Secretary, Secretariat, David Cooper, Dan Bondi Ogolla, Legal Advisor, Cyrie Sendashonga, Senior Programme Officer, Biosafety Unit, Jean-Pierre Le Danff, Programme Officer, Terrestrial Ecosystems, Olivier Jalbert, Principal Officer, Executive Direction and Management.
- WTO: Aidrian Otten, Director, IP Division, WTO; Jorge Vigano, counsellor, Trade and Environment, CTE; Bernie Kuiten, external relations officer, NGOs.
- UNCTAD: Salvano Briceno, Biotrade Initiative, Interim Coordinator; Rik Kutch Lojenga, Biotrade Initiative; Simonetta Zarrilli, Economic Affairs Officer, Division on International Trade in Goods and Services and Commodities; Bert-Jan Ottens, consultant (ProFound – adviser in development).
- WIPO: Richard Wilder, Programme Director, Global IP Issues, Programme 11; Nuno Carvalho, staff member.
- UNEP: Charlie Arden-Clarke, Senior Programme Officer, Economics and Trade.
- WHO: Jeremy Lauer.
- FAO: Pepe Esquinas, CGRFA; Sally Bunning, Tech Officer, Plant Division; Keith Hammond, Senior Officer, Animal Genetic Resources; Christian Hoste, senior adviser to Global Forum on Agricultural Research, NARS secretariat; Clive Stannard, CGRFA; Gordon Ramsey, Information Division; Nuria Urquia, CGRFA; Maria Zimmerman, Senior Agriculture Research Officer; Maria Grazia Queti.
- IPGRI: Cary Fowler, senior adviser to the director; Karin Troedsson, research fellow; Amy van Horn, law policy intern; Tony Hodgkin, IPGRI; Geoff Hawtin, Director General, IPGRI.
- South Centre: Rashid Kaukab.

European Commission

- Mr Jonathan Mogford, member of pharma unit, DG Enterprise.
- Mr Stefan Olsson and Mr Bail, member unit Environment A4. Development and environment (including CBD).
- Mr Gerasimos Apostolatos, SANCO.
- Mr Lutzeyer, DG Research
- Mr Hoogevelde, DG Development

Business organisations

- ASSINSEL and FIS: Mr Bernard Le Buanec, Secretary General; Patrick Heffer, assistant to the Secretary General.
- ICC: Michaela Eglin, Geneva representative.
- IFPMA: Dr Harvey E. Bale, Director General.
- UNICE: Brian Yorke

Non Governmental Organisations

- CIEL, Geneva Office: Matthew Stillwell.
- Quaker UN Office, Geneva: Brewster Grace, Representative.
- ICTSD: Ricardo Melendez, Director, ICTSD; Miguel Jimenez-Pont, Dialogues Programme Director.

- IISD: Mark Halle, Associate in Europe and Senior Programme Adviser, Trade and Sustainable Development; Tina Winqvist, Programme Officer.
- Action Aid: Ruchi Tripathi, Food Rights Campaign Team, UK.
- GAIA: Helena Paul.
- WWF: Aimee T. Gonzales, EPTSD Coordinator, WWF International.
- Quaker Peace and Service: Millius Palayiwa.
- WDM: Barry Coates.

Mission staff in Geneva

- Betty Berendson, Peru
- Christian Espinosa, First secretary, Ecuador
- Fancisco Cannabrava, Brazil
- Leo Palma, Philippines
- Lars Anderson, Norway
- Tony Sims, Joe Bradley, UK mission to WTO
- South African mission: Attie Swart (agriculture) , Patrick Krappie (TRIPS)
- Mohan Kumar, India
- Sven Blake, counsellor and Martin Loken, first secretary, Canada
- Roger Kamph, EU mission
- Rosemarie Luna Juarez, Guatemala
- Cleopas Zviawa, Zimbabwe
- Julio Alvarado, Bolivia
- Juliet Gichero, Kenya
- Lilia Carrera, Panama

National governments

UK Cabinet Office, Performance and Innovation Unit: Daniel Instone and Jill Johnson.

Individuals and businesses

- Novartis: Mr P Grubb, Corporate Intellectual Property; Mr W Smolders, Seeds/Patents and variety protection; Ms Patricia Ahl Goy, biodiversity side in seeds.
- Arthur Appleton, attorney in Geneva in International Trade Law.
- Pfizer: Dr Peter Richardson, Senior Assistant General Council and General Patent Council.
- Biswajit Dhar, Senior Fellow, Research and Information System for the Non-Aligned and Other Developing Countries, Delhi, India.
- Dwijen Rangnekar, Research Associate, School of Economics, Faculty of Human Sciences, Kingston University, Kingston, UK.

Dr Tewolde Berhan Gebre Egziabher, Environmental Protection Authority, Ethiopia.

Appendix 2: CBD

Article 2. Use of Terms

For the purposes of this Convention:

"*Biological diversity*" means the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

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

"*Biotechnology*" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

"*Country of origin of genetic resources*" means the country which possesses those genetic resources in *in-situ* conditions.

"*Country providing genetic resources*" means the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country.

"*Domesticated or cultivated species*" means species in which the evolutionary process has been influenced by humans to meet their needs.

"*Ecosystem*" means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit.

"*Ex-situ conservation*" means the conservation of components of biological diversity outside their natural habitats.

"*Genetic material*" means any material of plant, animal, microbial or other origin containing functional units of heredity.

"*Genetic resources*" means genetic material of actual or potential value.

"*Habitat*" means the place or type of site where an organism or population naturally occurs.

"*In-situ conditions*" means conditions where genetic resources exist within ecosystems and natural habitats and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"*In-situ conservation*" means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"*Protected area*," means a geographically defined area which is designated or regulated and managed to achieve specific conservation objectives.

"*Regional economic integration organisation*" means an organisation constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Convention and which has been duly authorised, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it.

"*Sustainable use*" means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

"*Technology*" includes biotechnology.

Appendix 3: A proposal for a global bio-collecting society¹⁶²

A3.1. Problems related to contracting over the use of indigenous knowledge

Contracts between indigenous groups and life sciences companies that relate to the use of indigenous knowledge raise a number of problems. Generally those contracts have to be negotiated in the absence of a well-defined set of property rights in that knowledge creating problems of uncertainty for both parties. Moreover the existence of a well-defined *sui generis* property rights regime in indigenous knowledge will not by itself guarantee that mutually beneficial exchanges between indigenous groups and companies will take place. To begin with, national *sui generis* indigenous intellectual property laws will, under the principle of territoriality, be enforceable only in the state in which they are enacted. A treaty on indigenous intellectual property rights that creates a minimum set of standards and entrenches the principle of national treatment remains for the time being a remote possibility¹⁶³. International free-riding remains a legitimate option under national regimes for indigenous knowledge. There are problems that relate to the enforcement and negotiation of the contract. Clearly, a contract between an indigenous group and a multinational corporation is not a contract between equally well-resourced parties. If, for example, a company breaches a term of a license agreement with an indigenous group that obliges it not to seek patents over life forms the indigenous group will have to be able to meet the costs of seeking enforcement of the agreement. Experience reduces uncertainty and here it is also worth noting that multinationals have a great deal of experience in negotiating licensing arrangements for the exploitation of intellectual property rights. Indigenous groups do not.

A fundamental problem in this area is the problem of pervasive imperfect information. When indigenous groups disclose to a company information about their uses of a plant they are not giving that company a product. The knowledge that they disclose reduces, to a degree, uncertainty in the state of nature. But only to a degree. One estimate has it that for every 5000 or so compounds that show some kind of activity in the early stages of testing one makes it to the stage of marketing¹⁶⁴. Whether a company can take advantage of the reduction of uncertainty that the disclosure of indigenous knowledge brings with it and deliver a product to the market depends on a host of factors including its scientific expertise, the behaviour of its competitors, the size of the market, the patenting position that the company can take and the regulatory hurdles it must overcome. Indigenous groups also have to cope with imperfect information. They do not know the value of the knowledge that they are disclosing¹⁶⁵ and whether the disclosure will, amongst other things, be treated in a way that is consistent with their cultural values and goals. They face the possibility that they will conclude *ex post* that their integration into the commerce in biodiversity was not worth the resulting changes to their traditional social world. Sometimes these information problems afflict both parties equally and in other

¹⁶² This proposal is based on the work of Peter Drahos in *European Intellectual Property Review*, Vol 22 Issue 6, June 2000, pp245-250.

¹⁶³ The World Intellectual Property Organisation began a series of fact-finding missions on traditional knowledge, innovation and culture of indigenous peoples, local communities and other holders of traditional knowledge and culture in June 1998. There is thus far no suggestion that a treaty is an appropriate normative response to the problems in this area. A draft report of WIPO's work is available on the web at <http://www.wipo.int/traditionalknowledge/>.

¹⁶⁴ Philip W. Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology*, OUP, Oxford, 1999, 366.

¹⁶⁵ The difficulties of valuing information in this area are discussed by Uma Suthersanen, 'Legal and Economic Considerations of Bioprospecting' in Michael Blakeney (ed.) *Intellectual Property Aspects of Ethnobiology*, Sweet and Maxwell, London, 1999, 72-78.

cases one party has superior information to the other¹⁶⁶. Never do any of the parties have perfect information.

The next section argues that these problems can be overcome through the creation of a Global Bio-Collecting Society.

A3.2. A Global Bio-Collecting Society

Collecting societies are common in the copyright area, where they serve copyright owners by reducing their transaction and enforcement costs¹⁶⁷. The proposal being put forward here, however, differs somewhat from the usual copyright collecting society model. Rather than having many bio-collecting societies at the national level, it would be better to have one global bio-collecting society (GBS). The operation of one GBS could be more easily scrutinised by the various interested actors than the operations of many national collecting societies. Better transparency, in short, would be one outcome of a GBS. It might also be argued that international organisations, for the most part, serve the interests of indigenous groups better than state organisations. States, not uncommonly, have been opponents of indigenous groups in the context of land claims and rights issues. Political-economic elites wielding the power of the state present the greatest danger to indigenous groups¹⁶⁸.

Another important difference between copyright collecting societies, which tend to serve the interests of copyright owners alone, and a GBS would be that the GBS would be chartered in a way that attended to the broader purposes that are specified in the CBD and perhaps also the International Undertaking On Plant Genetic Resources. The protection of indigenous knowledge by a GBS would be a primary rather than absolute duty.

A GBS would be best established as a private organisation outside the context of any treaty negotiation. The politicised waters of treaty negotiation make it difficult for any initiative to reach the shoreline. Funding for the GBS could come from the World Bank which in recent times has become much more interested in the role of knowledge in economic development¹⁶⁹. Importantly, membership would be open to both companies and indigenous groups and would be entirely optional. The idea would be that the GBS would stimulate a process of private ordering amongst companies and indigenous groups. If the services that the GBS provided turned out to be useful then corporations and indigenous groups would employ it. If not, then it would fold. The GBS could provide the following services:

1. It could act as the repository for community registers of indigenous knowledge¹⁷⁰. The GBS could assume the custody of a community register under strict obligations of confidentiality. There would be no registration system as such. A third party could find out that Indigenous

¹⁶⁶ For a discussion of symmetric and asymmetric information problems as they relate to contract law see Michael J. Trebilcock, *The Limits of Freedom of Contract*, Harvard University Press, Cambridge, Mass, and London, 1993, chapter 6 and 7.

¹⁶⁷ J. Thorpe, 'Regulating the Collective Exploitation of Copyright' 16 (1998) *Prometheus*, 317.

¹⁶⁸ Rosemary J. Coombe, 'Intellectual Property, Human Rights & Sovereignty: New Dilemmas In International Law Posed By The Recognition Of Indigenous Knowledge And The Conservation Of Biodiversity', 6 (1998) *Indiana Journal Of Global Legal Studies*, 59, 95.

¹⁶⁹ See, for example, U. Lele, W.H. Lesser, G. Horstkotte-Wesseler, (eds.), *Intellectual Property Rights in Agriculture: The World Bank's Role in Assisting Borrower and Member Countries*, World Bank, 1999.

¹⁷⁰ Community registers are forms of recording and documenting of indigenous knowledge that are authored and maintained by indigenous communities themselves. See Graham Dutfield, 'Protecting and Revisiting Traditional Ecological Knowledge: Intellectual Property Rights and Community Knowledge Databases in India' in Michael Blakeney (ed.) *Intellectual Property Aspects of Ethnobiology*, Sweet and Maxwell, London, 1999, 103, 117-121.

Group X had notified a community register with the GBS, and any further details that had been agreed to by Indigenous Group X. This notification system would be designed to trigger a dialogue between the indigenous group and the third party.

2. The GBS could, if requested, provide assistance with any contractual negotiation between a third party and an indigenous group. The GBS could maintain a register of independent legal experts who were willing to assist indigenous groups in such negotiations.
3. The GBS could provide a monitoring service for the use of indigenous knowledge. It can take from eight to fifteen years from the date of filing of patent for a pharmaceutical product to its eventual release on the market¹⁷¹. The long time frames involved in the use indigenous knowledge make the provision of a monitoring service vital. Monitoring might involve regular checks of patent applications around the world or requiring parties to report on the use of the licensed knowledge.
4. The GBS could have a dispute resolution function. As part of its structure it could have a committee, the member of which would be people of impeccable independence. They would publicly examine the conduct of the parties in the dispute and make recommendations. The aim of such a committee would be to gain the trust of industry and indigenous groups by virtue of its independence and impartiality. Failure to adhere to its recommendations would not be accompanied by any legal sanctions. A party ignoring its recommendations would be seen publicly to have done the wrong thing and in certain cases it might be excluded from the GBS altogether. Exclusion from this body would be a form of global shaming that might in fact act as a powerful deterrent to non-compliance with the committee's recommendations. A GBS dispute resolution procedure that operated in this way could conceivably avoid the "tyranny of lawyers"¹⁷².
5. The GBS could also have some sort of standard-setting function. It might, for example, develop an authoritative code of conduct for the negotiation of biodiversity prospecting contracts. For the purpose of standard-setting, it is important that the GBS have a tripartite process¹⁷³. Standards would be agreed in a process involving representatives from industry, indigenous groups and representatives from states.

One advantage of establishing the GBS in the way being suggested is that it would side-step the need for an international treaty in relation to national indigenous intellectual property rights. Membership of the GBS would itself constitute an acceptance that national indigenous intellectual property rights were to be respected. It is conceivable that respect for the use of indigenous knowledge could be secured in this way even if the state to which the indigenous group belonged had failed to provide legislative protection for indigenous knowledge. Clearly, the success of the GBS would depend upon the extent of its membership. If most indigenous and industry members participated, it could work. The question then is whether there are strong incentives for indigenous groups and companies to participate.

(a) Incentives for the Life Sciences Industry

¹⁷¹ Philip W. Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology*, OUP, Oxford, 1999, 366.

¹⁷² J. Braithwaite, 'Restorative Justice: Assessing Optimistic and Pessimistic Accounts', 25 (1999), *Crime and Justice*, 1, 106.

¹⁷³ For an analysis of the importance of tripartism in international organisations see J. Braithwaite and P. Drahos, *Global Business Regulation*, Cambridge University Press, Cambridge, 2000, 573.

The life sciences industry wants in this field freedom of contract, low search and transaction costs, and certainty of use. At the moment there is a proliferation of CBD laws at the national level that is, as observed earlier, creating uncertainty. Dealing with the GBS rather than potentially many national bureaucracies administering laws protecting indigenous intellectual property would lower industry's transaction costs. The GBS, by bringing together indigenous groups and members of the life sciences industry, would lower the search costs of both.

The GBS would play a critical role in obtaining certainty of use for companies. A company that acquired permission to use indigenous knowledge through the GBS process would have a defence against any other claims to the ownership of that knowledge that might surface later. Assume, for example, that Indigenous Group X had notified their knowledge to the GBS and that Company Y had been given permission to use that knowledge. Some time later Indigenous Group Z claims that that knowledge also belongs to it. Assume that this is genuinely a case of independent origination of knowledge. Under the GBS procedures Company Y would have a defence against Indigenous Group Z. However, Indigenous Group Z might be able to claim some of the money that Company Y paid to the GBS for the use of the knowledge. The critical thing is that it would be the GBS that would be centrally involved in the collection and distribution of the royalties and lump sums being paid to it. It is vital to separate companies from very difficult distributional issues such as these.

The issues relating to freedom of contract are also complex. States might be tempted to impose a host of mandatory conditions on parties wishing to make use of indigenous knowledge. But it is open to question whether this would serve either the interests of industry or indigenous groups. If the conditions prove too onerous, companies will not invest in utilising indigenous knowledge. This result would be Pareto inferior and dynamically inefficient. Allowing the state to set mandatory conditions also carries with it the risk of strategic rent-seeking behaviour by the state. The state may end up over-pricing the use of the indigenous knowledge. A non-profit GBS would be in a much better position to recommend to parties contractual conditions that were genuinely efficient.

(b) Incentives for Indigenous Groups

The GBS would help indigenous groups to solve the problem of international free-riding by offering them some prospect that the rights over their knowledge would be recognised by companies irrespective of where those companies were located. It would also offer them a means by which to enforce their rights. The GBS could absorb the monitoring costs that the use of indigenous knowledge would bring with it in the pharmaceutical sector. One of the functions of the GBS would be to provide help to indigenous groups with the negotiations of licensing agreements. A GBS could also, when it came to the collection and distribution of royalties, deal directly with indigenous groups, thereby avoiding state apparatuses. Bearing in mind the problem of systemic corruption in some developing countries this would, on the whole, be a good thing¹⁷⁴. Indigenous groups have absolutely nothing to lose in experimenting with a new form of distribution since it has been estimated that "less than 0.001 percent of the profits

¹⁷⁴ The problem of systemic corruption would also likely defeat the economic benefits that are argued to flow from *state* run biodiversity cartels (see the discussion of such cartels in G. Dutfield, *Intellectual Property Rights, Trade and Biodiversity*, Earthscan Publications, London, 2000, 116-17). The model being proposed here would facilitate private negotiations between companies and indigenous groups while taking advantage of collective organisation to solve problems of transaction and enforcement costs. It would deliver better dynamic efficiency than the cartel model.

from drugs that originated from traditional medicines have ever gone to the indigenous peoples who led researchers to them¹⁷⁵.

The GBS would be in many ways a unique creature - a private global organisation facilitating private ordering between international companies and local actors so as to champion the global public purposes for which it was chartered. The role that has been sketched for it here will no doubt raise as many questions in the minds of readers as it answers. But on the face of it at least there are enough reasons to think that a GBS might deal with some of the needs that face indigenous groups and the life sciences industry as they begin to forge partnerships in the commerce of biodiversity.

¹⁷⁵ Posey cited in Rosemary J. Coombe, 'Intellectual Property, Human Rights & Sovereignty: New Dilemmas In International Law Posed By The Recognition Of Indigenous Knowledge And The Conservation Of Biodiversity', 6 (1998) *Indiana Journal Of Global Legal Studies*, 59, 96.