

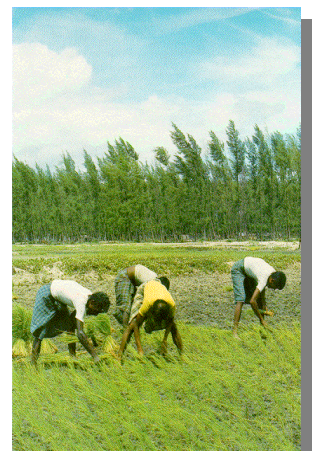
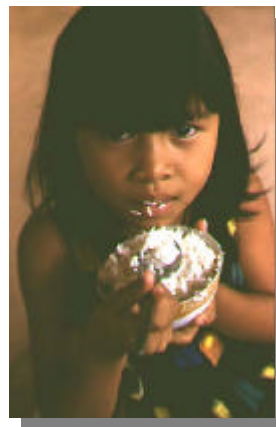


Biodiversity & Intellectual Property Rights:



Reviewing Intellectual Property Rights in Light of the Objectives of the Convention on Biological Diversity

**Joint Discussion Paper
March, 2001**



This paper was researched and written by Catherine Monagle for CIEL and WWF International. This paper aims to provide a platform for further discussions on policy alternatives. It does not intend to form a definitive statement of policy recommendations.

The author would like to thank David Downes for his extensive contribution to an initial draft of this paper, as well as Biswajit Dhar, Aimee Gonzales and Matthew Stilwell for their comments.

The views in this paper are those of the author and do not necessarily reflect those of CIEL or of WWF. The information is current as of February 2001.

For comments and/or queries on this paper, please contact:

Catherine Monagle

Attorney
Center for International Environmental Law (CIEL)
European Office
160a Rte de Florissant
1231 Conches
Switzerland
Tel: +41 22 789 07 38
Fax: +41 22 789 05 00
E-mail: cmonagle@ciel.org
Website: www.ciel.org

Aimee T. Gonzales

Senior Policy Adviser, Trade & Investment Unit
WWF International
Ave du Mont-Blanc
1196 Gland
Switzerland
Tel: +41 22 364 9002
Fax: +41 22 364 8219
E-mail: agonzales@wwfint.org
Website: www.panda.org

For other publications or more information,
please contact:

Delwyn Dupuis

WWF International
Ave du Mont-Blanc
1196 Gland
Switzerland
Tel: +41 22 364 9012
Fax: +41 22 364 8219
E-mail: ddupuis@wwfint.org
Website: www.panda.org

Published March 2001 by WWF – World Wide Fund For Nature (Formerly World Wildlife Fund), Gland, Switzerland and by CIEL, Geneva, Switzerland. Any reproduction in full or in part of this publication must mention the title and credit the above-mentioned publishers as the copyright owners. © Text 2001 WWF/CIEL. All rights reserved.

The material and the geographical designations in this report do not imply the expression of any opinion whatsoever on the part of WWF and CIEL concerning the legal status of any country, territory, or area, or concerning the delimitation of its frontiers or boundaries.

Table of Contents

Introduction	1
Recommendations	2
I. Intellectual Property and the Convention on Biological Diversity (CBD)	3
a. Access to and the Fair and Equitable Sharing of Benefits arising from the Utilisation of Genetic Resources	4
b. Preservation of and Respect for the Knowledge, Innovations, and Practices of Indigenous and Local Communities	4
c. Transfer of Technology	5
d. Conservation and Sustainable Use of Biological Diversity	7
II. Intellectual property and the WTO Agreement of Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)	8
a. Implementing the TRIPS Agreement	8
b. Patent Protection	9
c. <i>Sui generis</i> Systems of Plant Variety Protection	9
d. Reviewing and amending the TRIPS Agreement	9
e. WTO Dispute Settlement Mechanism	10
III. Key Issues	12
a. The TRIPS Agreement may affect Access to and the Fair and Equitable Sharing of Benefits arising from the Utilisation of Genetic Resources	12
b. The TRIPS Agreement may affect Preservation of and Respect for the Knowledge, Innovations, and Practices of Indigenous and Local Communities	13
c. The TRIPS Agreement may affect the Transfer of Technology	15
d. The TRIPS Agreement may affect the Conservation and Sustainable Use of Biological Diversity	18
IV. Recommendations for Action	19
a. At the International Level	19
b. At the National Level	22
Endnotes	25

Introduction

The relationship between the objectives of the Convention on Biological Diversity (CBD) and intellectual property rights (IPRs) is the subject of continuing debate. Equally controversial is the effect of the Agreement on Trade-Related Aspects of Intellectual property (TRIPS Agreement) – one of the agreements binding on Members of the World Trade Organisation (WTO) – on the achievement of the CBD's objectives and on sustainable development generally.

Progress in resolving these complex issues has been slow. In this discussion paper, CIEL and WWF offer an overview of progress at the WTO and the CBD and recommend some ways forward. We explore the relationships between these legal frameworks, and outline key steps that CBD parties and WTO Members – who comprise many of the same countries – should take at the international and national levels. In particular, to support these key steps, we call for action by the Conference of the Parties (COP) and subsidiary bodies of the CBD, and by the WTO's Council for TRIPS and General Council.

This paper is divided into four sections. Parts I and II review the relevant provisions of the CBD and the TRIPS Agreement respectively. These sections highlight the IPR related aspects of the CBD, and the biodiversity related aspects of TRIPS. The analysis in these sections is drawn together in Part III, which summarises the most important issues arising from the substantive linkages between the CBD's objectives, IPRs and the TRIPS Agreement. Responding to these issues, Part IV offers recommendations to CBD Parties and WTO Members for decisions or procedures at the international level – in particular under the auspices of the CBD and the WTO – and at the national level through legislative and policy measures.

Recommendations

In summary –

CBD Parties should:

- ◆ Insist on permanent observer status for the CBD in the Council for TRIPS.
- ◆ Develop strong guidelines for access and benefit sharing, including minimum binding requirements for implementation in national law.
- ◆ Encourage and assist the CBD Secretariat to compile further case studies and empirical evidence on the relationship between IPRs, the TRIPS Agreement and the CBD, particularly focusing on the relationship of IPRs and access and benefit sharing, and the impact of IPRs on technology transfer.
- ◆ Support the conclusion of a binding International Undertaking (IU).

WTO Members should:

- ◆ Grant the CBD permanent observer status in the Council for TRIPS.
- ◆ Revise the requirements for patent applications to prevent misappropriation of knowledge relating to genetic resources and to ensure consistency with access and benefit sharing regimes pursuant to the CBD. Patent applicants should be required to state the country of origin, and prove rightful or lawful access to the knowledge or resource.
- ◆ Extend the period for implementation of Article 27.3(b) for at least 5 years after the conclusion of a substantive review.
- ◆ Complete a substantive review of Article 27.3(b) and use the review to harmonise the TRIPS Agreement with the CBD and the International Undertaking.
- ◆ Expand the exceptions to patentability under Article 27.3(b).
- ◆ Resist attempts to reduce flexibility in defining *sui generis* systems.
- ◆ Undertake a “sustainability review” under Article 71.1 of the TRIPS Agreement.
- ◆ Take measures to avoid disputes from arising in relation to IPRs and the provisions of the CBD and the TRIPS Agreement. These measures should include a moratorium on dispute resolution relating to TRIPS, incorporate CBD based expertise in the dispute resolution process, and the undertaking of an affirmation that, in the event of a conflict, the TRIPS agreement should not interfere with a Party’s implementation of CBD obligations.

At national level policy makers should:

- ◆ Develop and implement access and benefit sharing regimes with minimum and binding standards in national legislation
- ◆ Define core intellectual property concepts carefully in national legislation.
- ◆ Utilise the exclusions to life patenting under Article 27.3(b).
- ◆ Ensure *sui generis* systems are consistent with CBD obligations.
- ◆ Record experiences of TRIPS/CBD tensions.
- ◆ Provide a forum to allow indigenous people to develop strategies on the preservation and protection of traditional knowledge.
- ◆ Consider the development of registries of traditional knowledge.
- ◆ Ensure that national intellectual property offices are adequately resourced.
- ◆ Assist in the articulation of human rights principles as they relate to intellectual property rights.

1. Intellectual Property & the Convention on Biological Diversity (CBD)

The CBD's objectives are (1) to conserve biological diversity, (2) to promote the sustainable use of its components, and (3) to achieve fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.¹ These objectives find expression in the provisions of the CBD, many of which are affected, directly or indirectly, by IPRs.

The relevance of IPRs stems from their role as one of society's principal mechanisms for protecting and enforcing control over information.² The information encoded in genetic resources is increasingly of commercial value – as a source of new crop and plant varieties, pharmaceuticals, herbicides and pesticides, as well as new biotechnological products and processes.

Intellectual property rights are private rights. As an incentive for innovation, they grant their holder the ability to exclude others from certain activities, such as using a product or process, for a defined period of time. The control afforded by IP protection thus enables right holders to limit who can use the resource, and so claim the benefits of commercialisation with little competition. The patent system contemplated by the TRIPS Agreement, for example, allows the holder of a product patent to prevent third parties from making, using, offering for sale, selling or importing the product.³

The scope of the exclusive rights created by IPRs defines who can use the information contained in genetic resources, and so influences the distribution of the benefits flowing from this use.⁴ In these ways, and others, IPRs will affect who shares in the benefits arising from genetic resources, and the type of technology developed from genetic resources, with implications for the conservation and use of biological diversity. As a result of the value associated with IPRs, there is increasing pressure by commercial interests to gain intellectual property rights over genetic resources. This pressure, and the resulting IPR systems, is raising challenges for policy-makers who seek to give effect to the objectives of the CBD.

The relationship between the CBD and IPRs has been considered by the CBD Conference of the Parties (COP) in a number of decisions. The COP called for cooperation with the WTO on IPR-related issues (decision III/15); noted the need for further work to develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the TRIPS Agreement and CBD (decision III/17); and stressed “the need to ensure consistency in implementing the Convention on Biological Diversity and the World Trade Organisation agreements, including the Agreement on Trade-Related Aspects of Intellectual Property Rights” (decision IV/15). It has also invited the WTO to take into account relevant provisions of the Convention, their interrelationship with the provisions of the TRIPS Agreement, and to further explore this interrelationship (decision V/26). While related to a number of aspects of biodiversity conservation, IPRs are proving particularly relevant to provisions of the CBD that govern the following four inter-related areas:

a. Access to and the Fair and Equitable Sharing of Benefits arising from the Utilisation of Genetic Resources

By encouraging its parties to provide access to and to equitably share the benefits arising from the utilisation of genetic resources, the CBD seeks to establish incentives to conserve biodiversity.⁵ Its approach to “access and benefit sharing” is reflected in a number of the CBD’s provisions.

The CBD’s approach is first of all based on the fundamental premise that nation states have sovereign rights over the biological diversity within their territory (Preamble and Article 15(1)). The CBD also recognises that national governments have the authority to determine access to these resources in accordance with national legislation (Article 15(1)). It provides that access to genetic resources must be obtained with the “prior informed consent” of the CBD party, and on mutually agreed terms (Article 15(4) and (5)). The CBD envisages the use of legal measures, that could feasibly include IPRs (Article 15(7)), by calling on Parties to take legislative, administrative or policy measures to ensure the benefits arising from research, development and commercial use of genetic resources are shared in an equitable way with the provider of the genetic resources.⁶

The COP has established a number of subsidiary bodies to consider access and benefit sharing. First, it has established a “Panel of Experts” on access and benefit sharing whose role is to develop “a common understanding of basic concepts and to explore all options for access and benefit-sharing on mutually agreed terms including guiding principles, guidelines, and codes of best practice for access and benefit-sharing arrangements.”⁷ The COP, at its fifth meeting, requested the Panel to assess the experience by the users and providers of genetic resources of benefit sharing. Second, it has established an “Ad Hoc Open-ended Working Group” on access and benefit sharing, comprised of representatives nominated by governments and regional economic integration organisations, to develop guidelines and other approaches on access and benefit sharing, in light of other CBD objectives, for submission to the COP. The work of these two bodies will be complemented by comments from Parties on the role of intellectual property in access and benefit sharing, in response to the COP’s request in decision V/26.

It is clear from the work of the CBD that the linkages between IPRs and access and benefit sharing are significant. Consequently, and as discussed below in Part III, the evolution of IPR systems – including those required by the TRIPS Agreement – may therefore have significant implications for the achievement of the CBD’s objectives.

b. Preservation of and Respect for the Knowledge, Innovations, and Practices of Indigenous and Local Communities

Closely related to the CBD’s provisions on access and benefit sharing are those regarding the preservation of and respect for the knowledge, innovation and practices of indigenous and local communities. This “traditional knowledge” has often been conserved by indigenous and local communities through informal, collective processes extending across generations. This knowledge – regarding, for example, the long-term selective breeding of food crops, and knowledge of medicinal plants – provides an important source of information for the sustainable management of biological diversity, and for the development of new, socially beneficial products.

The CBD calls on Parties to “respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity” in Article 8(j).⁸ This article also encourages the wider application of these practices, and echoes other provisions on the importance of equitable access and benefit sharing.⁹

A diversity of views has been expressed about the relationship between traditional knowledge and IPRs. Some commentators argue that IPRs can provide an incentive for continued investment in the preservation of these practices. Other commentators argue that traditional knowledge generally falls outside the parameters of protection offered by current IPR regimes, and that these regimes may enable the knowledge of indigenous and local communities to be misappropriated by others. These views are not mutually exclusive, and there are examples where both are true. Nevertheless there are a growing number of instances in which IPRs have been used to gain control over traditional knowledge, without provision for benefit sharing (See Box 1).

Whether the knowledge, innovations and practices of indigenous and local communities can and should be protected by IPR systems remains a controversial issue. What is clear, however, is that to remain consistent with the CBD, IPRs should not be used to undermine efforts to protect the equitable sharing of benefits, and the preservation and respect for the knowledge, innovations and practices of indigenous and local communities.

c. Transfer of Technology

In addition to affecting access and benefit sharing, and the protection of traditional knowledge, IPRs may influence the nature of technologies developed from genetic resources, and how those technologies are transferred and used.

The development and transfer of appropriate technology is important for the successful realisation of the CBD’s objectives.¹⁶ The CBD refers to 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.” It requires Parties to transfer technology to developing countries on “fair and most favourable terms”, including on concessional and preferential terms where mutually agreed (Article 16(2)).

The CBD recognises that the development and transfer of technology will be affected by IPRs. Where technology is IPR protected, it requires access to be provided on terms that are “consistent with the adequate and effective protection” of those rights (Article 16(2)). It also requires that, where a developing country has provided access to genetic resources, that country should be provided with access to technology that makes use of those resources (Article 16(3)). Notably, the CBD requires Parties to co-operate, subject to national legislation and international law, to ensure that IPRs “are supportive of and do not run counter to” the CBD’s objectives (Article 16(5)).

The relationship between IPRs and technology transfer under the CBD is multifaceted. IPRs (and the market incentives that accompany them) should be evaluated for their effect on the nature of technology developed from genetic resources, and on the transfer of these technologies. IPRs will also need to be evaluated to ensure that they do not “run counter” to the objectives of the CBD. As noted by the CBD Secretariat,

“Due to the rapid development of technologies, particularly biotechnology, further consideration of the impacts of intellectual property rights on the achievement of the objectives of the Convention, including in facilitating access to and transfer of technology is urgently needed.”¹⁷

Box 1 - Misappropriation of Indigenous and Local Community Knowledge

Below are a few examples of cases in which indigenous and local community knowledge has been misappropriated through the use of IPRs.

- ◆ Basmati – a patent was granted by the US Patent and Trademark Office (PTO) to RiceTec, a Texas based company over rice derived from traditional “Basmati” rice – a product long associated with South Asia and economically significant in that region.¹⁰ The Indian government has successfully challenged 4 of the 20 claims made by RiceTec. The validity of the other claims, however, remains unchallenged.¹¹
- ◆ Neem – a patent was granted by the European Patent Office to the US Department of Agriculture and the corporation W.R. Grace over the process of extracting oil from the Neem tree, which has been used for generations by communities in India. After challenge by organisations representing local communities, this patent was overturned in May 2000. Although overturned in Europe, many other neem-related patents remain unchallenged in the United States.¹²
- ◆ Ayahuasca - a patent was granted by the US PTO to a US citizen over a variety of the Ayahuasca vine, which has been used for generations by indigenous people in the Amazon for ceremonial and healing purposes.¹³ After challenge by the Coordinating Body for Indigenous Organisations of the Amazon Basin, the Coalition for Amazonian Peoples and their Environment, and the Center for International Environmental Law, the patent was overturned in 1999 for lacking novelty. The decision of the US PTO, however, failed to consider whether patents should be prohibited on the public policy ground that the plant is sacred.
- ◆ Sweet Berries – a patent was granted to the University of Wisconsin over a super sweet substance derived from the berries of the plant *Pentadiplandra brazzeana*, from Gabon. Licensing arrangements will lead to the commercialisation of the product.¹⁴ The compound has been genetically engineered into maize plants, from which it will be manufactured as a low calorie sweetener that is likely to earn a significant return.
- ◆ Turmeric – a patent was granted to researchers at the University of Mississippi Medical Center over a "method of promoting healing of a wound by administering turmeric to a patient afflicted with a wound". Turmeric has been used in India for centuries for its medicinal and culinary qualities, and has been used by followers of traditional medicine to heal wounds. The Indian Council for Scientific and Industrial Research (CSIR) launched proceedings against the Medical Center to reverse the patent grant on the grounds that the patent application failed to meet the requirement of novelty.¹⁵

While some patents that misappropriate traditional knowledge – often termed “bio-piracy” – have been overturned, countless others remain unchallenged. Overturning a patent is a time-consuming, expensive and difficult process and relies on the assertiveness of affected communities, the assistance of NGOs, and pro bono legal support.

d. Conservation and Sustainable Use of Biological Diversity

An overarching objective of the CBD is encouraging the conservation and sustainable use of the components of biological diversity.¹⁸ This objective encompasses many of the issues raised above, and requires consideration of additional, often indirect, impacts of IPRs on the conservation and sustainable use of biodiversity.

Among its many obligations relating to conservation and sustainable use, the CBD requires Parties to integrate considerations relating to conservation and sustainable use into national decision-making (Article 10). It requires its Parties to adopt measures relating to the use of biological resources to avoid or minimise adverse impacts on biological diversity (Article 10(b)). Further, Parties are encouraged to integrate the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies (Article 6(b)). Parties are responsible for identifying processes and categories of activities that have or are likely to have significant adverse impacts on biological diversity and monitoring their effects (Article 7(c)). The granting of IPRs could, arguably, be such a category of activity.

The CBD also includes a number of obligations relating to the conservation of *in situ* biological diversity. For example, it requires Parties to “control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts” (Article 8(g)). Implementation of these obligations will be particularly important in relation to the conservation of agricultural biodiversity, where IPRs provide a strong incentive for the development of genetically modified plant varieties.

2. Intellectual Property & the WTO Agreement of Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)

The pre-eminent international agreement regarding intellectual property rights is the World Trade Organisation's TRIPS Agreement. This Agreement, which was agreed during the Uruguay Round of trade negotiations, establishes uniform, minimum standards for the protection and enforcement of IPRs by all WTO Members.

According to its preamble, the TRIPS Agreement is designed to “promote effective and adequate protection of intellectual property rights” and to “reduce distortions and impediments to international trade” resulting from the enforcement of IPRs. According to its objectives, included in Article 7, it seeks to promote technological innovation and transfer, in a manner “conducive to social and economic welfare, and to a balance of rights and obligations”.

The Agreement covers a broad range of intellectual property rights, including copyright, trademarks, geographical indications, trade secrets, and patents. It requires Members to grant IPRs to the nationals of other Members on the same terms as they do their own nationals (“national treatment” - Article 3), and to extend the same favourable terms they grant to the national of any Member to the nationals of every other Member (“most-favoured nation” - Article 4).

The TRIPS Agreement includes a number of forms of IPR with implications for biodiversity conservation including patents, and “*sui generis* systems” for plant variety protection.¹⁹ Patents and *sui generis* systems are relevant to the implementation of the CBD as they play a key role in defining who gains access to information about genetic resources, how the benefits are shared (including with traditional communities), and what technologies are developed and transferred with implications for conservation and sustainable use of biological diversity.

a. Implementing the TRIPS Agreement

In consideration of the complexity of the obligations contained in the Agreement, developing countries had a transition period of five years - until January 1, 2000 - for implementation.²⁰ From that date, developing countries have an additional five years to extend patent protection over products in those areas of technology for which they offered no protection when the WTO Agreement entered into force.²¹ The least developed countries have a total of ten years within which they must implement TRIPS.²²

For developing countries, the transition period has passed. This timeframe, for reasons including lack of capacity and poor financial assistance from developed countries, has proved inadequate. Some have not yet been able to implement their obligations. Others

have responded to the time frame by adopting ready-made models originating from the developed world.²³

b. Patent Protection

The TRIPS Agreement requires Members to offer patent protection for inventions in all areas of technology, whether products or processes, that are new, involve an inventive step, and are capable of industrial application (Article 27.1).²⁴ This requirement, which is cast in broad terms, is subject to some important exceptions, which may be relevant to the successful implementation of the objectives of the CBD. First, Members may exclude inventions from patentability where it 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" (Article 27.2). Second, while Members are required to grant patents over micro-organisms as well as nonbiological and essentially biological processes for the production of plants and animals, they are not required to grant patents over plants or animals (Article 27.3(b)). Third, Members may provide limited exceptions to the exclusive rights conferred by patents, subject to certain qualifications (Article 30). Finally, Members may permit use of the patented invention by third parties without the authorisation of the patent owner in certain circumstances (Article 31). So far, the scope and utility of these provisions in ensuring compatibility with CBD objectives remains unclear at the WTO.

c. *Sui Generis* Systems of Plant Variety Protection

The exception to patentability in Article 27.3(b) also gives rise to the requirement to offer *sui generis* protection over plant varieties. Article 27.3(b) provides that Members must provide protection for plant varieties, either in the form of patents or an "effective *sui generis* system". A *sui generis* system is a system for the protection of plant varieties that is chosen by the Member, and can be designed to accommodate the particular needs of that Member. Members can also choose a combination of patents and *sui generis* protection.²⁵

The interpretation and application of these provisions on plant variety protection will have significant implications for the implementation of the CBD. How the rights to information are allocated under the TRIPS Agreement will impact on how benefits from the use of genetic resources are shared. For example, although a high proportion of *in situ* biodiversity and related traditional knowledge, innovations and practices, are found in developing countries, most patents relating to biological resources are granted for research undertaken in developed countries. *Sui generis* protection may, if appropriately defined, provide a tool for implementing the CBD's objectives, including access and benefit sharing, and technology transfer. Inappropriately defined, *sui generis* protection may frustrate the CBD objectives, particularly access and benefit sharing, the preservation of the practices of indigenous and local communities, and technology transfer. The implications of patents and *sui generis* protection for various CBD obligations is discussed in more detail below in Section III.

d. Reviewing and amending the TRIPS Agreement

The TRIPS Agreement includes at least two review processes of relevance to policy-makers seeking to ensure achievement of the CBD's objectives: the review of Article 27.3

(b), and the review of the whole TRIPS Agreement under Article 71.1.

Article 27.3(b) required Members to review its provisions during 1999. The review, however, remains inconclusive. Some developed countries have argued that the review is over, or that it is a review merely of Article 27.3(b)'s implementation. Developing countries, by contrast, insist it is a review of the substance of Article 27.3(b). In the March 2000 TRIPS Council meeting the Chair suggested the following list of substantive issues for discussion. Although it has not yet been formally adopted, the list provides a useful division of issues arising under Article 27.3(b):

- ◆ The link between Article 27.3(b) and the developmental and economic interests of developing countries;
- ◆ Exclusions to patentability and the definition of terms used;
- ◆ *Sui generis* systems and their relationship with the UPOV system of plant variety protection;
- ◆ Ethical questions about the patenting of life forms;
- ◆ Prior informed consent and benefit sharing; and
- ◆ Traditional knowledge and farmers rights.

A number of these – including prior informed consent and benefit sharing, traditional knowledge and farmer's rights, as well as *sui generis* protection and its relationship with UPOV – are relevant to the CBD.

The importance of the Article 27.3(b) review has been acknowledged by the CBD's Conference of the Parties. The COP stressed the need to promote "increased mutual supportiveness and integration of biological diversity concerns and the protection of intellectual property rights", and invited the WTO to consider how to achieve these objectives in light of CBD Article 16(5), taking into account the planned review of Article 27.3(b).²⁶ So far, the WTO has not undertaken this discussion.

A second and broader review of the TRIPS Agreement is contemplated in Article 71.1. This article, entitled *Review and Amendment*, requires the TRIPS Council to review the implementation of the TRIPS Agreement, commencing in 2000. So far, the precise scope of the review has not been formally agreed, although the WTO General Council has stated that "mandated reviews should address the impact of the agreements concerned on the trade and development prospects of developing countries."²⁷ Arguably, the review should examine whether the TRIPS Agreement is meeting its objectives as established in its preamble and Article 7, and the broader objectives of the WTO, including raising standards of living "in accordance with the objective of sustainable development". Such a "sustainability review" of the TRIPS Agreement under Article 71.1 would also allow WTO Members to ensure that implementation of the IPR systems required by the TRIPS Agreement is supportive of, and does not run counter to, the objectives of the CBD as required by Article 16(5) of that agreement.

e. Dispute Settlement

Perhaps the TRIPS Agreement's greatest source of influence arises from its enforcement procedures. The WTO's Understanding on the Settlement of Disputes (DSU) establishes a binding dispute settlement mechanism.²⁸ If a Member fails to abide by a decision of the dispute settlement mechanism, the complaining Member may be authorised to impose

trade sanctions on the other party. Although it is among the most powerful international dispute settlement systems, it has been criticised for inadequate transparency, insufficient mechanisms for gaining access to non-trade expertise, and sometimes inappropriate decisions regarding the competing goals of trade liberalisation and environmental protection. Where the subject matter of the WTO agreements and other international agreements interrelate, the existence of the dispute settlement mechanism is one factor that lends practical and political strength to the WTO agreements. It is thus important in designing recommendations to resolve tensions between the CBD and the TRIPS Agreement, to consider this factor.²⁹

3. Key Issues

The relationship between IPRs and the provisions of the TRIPS Agreement and the CBD gives rise to a range of issues. Many policy-makers and members of civil society are concerned that the TRIPS Agreement promotes private commercial interests at the expense of other important public policy objectives, such as those contained in the CBD. Specifically they are concerned that the TRIPS Agreement is creating serious challenges to the successful implementation of the CBD, including in relation to the four issues discussed in Part I - access and benefit sharing, protection of traditional knowledge, technology transfer, and the conservation and sustainable use of biological diversity. This section draws together the discussion of IPR related aspects of the CBD included in Part I and the discussion of biodiversity related aspects of TRIPS included in Part II, and summarises the most important issues arising from the substantive linkages between the CBD's objectives, IPRs and the TRIPS Agreement.

a. The TRIPS Agreement may affect access to and the fair and equitable sharing of benefits arising from the utilisation of genetic resources

Access and benefit sharing under the CBD may be affected by the IPR systems required by the TRIPS Agreement. IPRs are often granted to individuals of one country over genetic resources obtained from another country. Consequently, if the objectives of the CBD are to be achieved, IPR holders should have gained access to genetic resources with prior informed consent, on mutually agreed terms, and with provisions to guarantee fair and equitable sharing of benefits. This, however, is not always the case. IPRs required or permitted by the TRIPS Agreement may in certain circumstances undermine efforts to ensure equitable benefit sharing – in both countries that use genetic resources, and that provide access to genetic resources.

Countries that use genetic resources in a process of formal innovation (in many cases, developed countries) have an incentive to limit efforts to promote benefit sharing. In some of these countries, IPRs have provided a tool for individuals and corporations to gain access to the genetic resources of others without sharing the benefits. As noted in Box 1, patent offices in some developed countries have granted patents over genetic resources – including those of local and indigenous communities from the developing world – without the consent of their custodians, and without any benefits flowing to them. Similarly, individuals or corporations may use over-broad patent claims to appropriate material obtained from gene banks (originating from traditional landraces, and held in trust for the international community).³⁰ Claims of these types are clearly inconsistent with the CBD's objectives, and should be the subject of international cooperation to bring them into conformity with the CBD, as required by Article 16(5) of the CBD. In these countries, at a minimum, patent applications should be considered only where evidence of the arrangements made for benefit sharing is provided.

Countries that provide access to genetic resources (in many cases, developing countries) have an incentive to seek strong benefit sharing measures. In these countries, however, the TRIPS Agreement may be used to undermine attempts to develop and use benefit-sharing measures such as national legislation to require patent holders to share their profits with

the providers of genetic resources, or to provide licenses for the use and development of the patented product or process. In these cases, such measures may conceivably be challenged in bilateral discussions, and ultimately at the WTO, on the basis that they “unreasonably prejudice” the interests of the patent owner (TRIPS Agreement, Article 30). The success or failure of any such claim is difficult to predict with certainty, and will depend on the interpretation of the TRIPS Agreement’s obligations on IPRs and its exceptions. For these countries, favourable interpretation of TRIPS patents and *sui generis* obligations, and expansive interpretation of applicable exceptions, will help ensure the TRIPS Agreement is not used to undermine effective attempts to ensure fair benefit sharing, and to implement the objectives of the CBD.

While IPRs may, in certain cases, undermine efforts to implement the CBD’s objectives, they may – if designed carefully and implemented in light of national priorities – also provide a useful tool to help share the benefits arising from the use of genetic resources. In particular, *sui generis* systems, combined with other policy measures, may provide a tool to ensure that communities that provide access to genetic resources are guaranteed a share in the benefits arising from their use. The role of *sui generis* systems in the fair sharing of benefits from traditional knowledge is further discussed in the next section.

Finally, no discussion of access and benefit sharing is complete without reference to the special situation of plant genetic resources for food and agriculture, and the relationship between the CBD, the TRIPS Agreement, and the International Undertaking (IU), an international agreement on genetic resources for food and agriculture. The IU, which addresses issues of access and benefit sharing, may eventually become a binding protocol to the CBD and is, for this reason and others, relevant to a discussion about the role and limits of IPRs. The relationship of the IU, the CBD and the TRIPS Agreement is further discussed in Box 2.

b. The TRIPS Agreement may affect preservation of and respect for the knowledge, innovations, and practices of indigenous and local communities

Like the relationship between IPRs and access and benefit sharing, the relationship between IPRs and the preservation of and respect for the knowledge, innovations and practices of indigenous knowledge and local communities is a subject of much debate.³¹

As noted above, existing IPR systems such as patents may increase the risk of misappropriation of traditional knowledge. There is also concern that existing IPRs fail to provide positive incentives for local and indigenous communities to preserve and, if they wish, to capitalise on their traditional knowledge. It is clear that existing IPR systems such as patents are largely inappropriate to protect traditional knowledge: they are often expensive and difficult to access, and are unable to safeguard traditional knowledge that is often communally held and passed through the generations. Other forms of IPRs, such as geographical indications, copyright and trademarks may be used by some communities, but their effectiveness and breadth of coverage is limited.

Supporters of the existing IPR systems embodied in the TRIPS Agreement argue that IPRs provide incentives for continued investment by local and indigenous communities in the preservation of their biodiversity-related cultural heritage; if existing IPRs are combined with benefit-sharing arrangements (included, for example, in contracts for

BOX 2 – The International Undertaking on Plant Genetic Resources for Food and Agriculture (IU)

The International Undertaking on Plant Genetic Resources for Food and Agriculture (IU), being revised under the Commission on Genetic Resources for Food and Agriculture of the FAO, is directly relevant to both the CBD and the TRIPS Agreement. One hundred and thirteen (113) countries have adhered to the non-binding IU. The objectives of the IU are the "conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security".³² The IU prescribes a multilateral system of access and benefit sharing for genetic resources for food and agriculture. It is based on the premise that the free exchange of genetic resources is essential to food security and the conservation of genetic resources for food and agriculture.³³

The legal basis of the IU was a topic of discussion at the February 2001 meeting of the Contact Group of the Commission on Genetic Resources for Food and Agriculture (CGRFA). It is likely that the IU will become a legally binding agreement and may form a protocol to the CBD. Other options include the adoption of the IU as an agreement for the implementation of the CBD, or as an agreement linked to the constitution of the FAO.³⁴ Whichever option for the IU's legal basis is taken, the IU will stand with the CBD and TRIPS as one of a triad of international agreements influencing access to and the sharing of benefits from the exploitation of genetic resources.

The IU, like the CBD, sits in an uneasy relationship with the TRIPS Agreement. This is the case in relation to both access to resources as well as the sharing of benefits resulting from commercialisation. Firstly, the TRIPS Agreement does not prohibit Members from granting patents over plant genetic resources. Patents give the patent holder exclusive rights over the resource for the duration of the patent, which they are likely to exercise by withholding access to the resource. If a patent is granted over resources that are covered by the IU, the resource may become unavailable to Members of the IU who wish to access it through the system of multilateral access. The system of facilitated access is an essential feature of the IU. To respond to this problem, the current draft of the IU includes bracketed text representing two options. The first option prohibits recipients of material from the multilateral system from claiming IPRs that would limit facilitated access to the resource. The second option simply prohibits the recipient from claiming IPRs over material received via the system of facilitated access.³⁵

Secondly, there is no mechanism in TRIPS to ensure that benefits derived from patent protection over genetic resources relating to food and agriculture are collected and distributed fairly and equitably. The bracketed negotiating text of the IU makes provision that where IPRs are obtained over a product developed from resources received through the facilitated access system of the IU (assuming the abovementioned brackets relating to access have not been adopted or do not apply), and the IPR creates a restriction on further access for research and plant breeding, the rights holder shall pay an equitable royalty to a mechanism set up under the IU.³⁶ Where there is no restriction on access for research and breeding, payment of a royalty is encouraged. These provisions may limit the extent of private rights created by the TRIPS Agreement and so may reasonably prejudice the interests of the patent holder.

The IU was developed on the basis of the principle that plant genetic resources are a common heritage of humankind and should be available without restriction. The IU then began the process of harmonization with the CBD, which saw it incorporate the notion of state sovereignty over genetic resources. The CBD for its part, acknowledged the "special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions".³⁷ The two agreements work increasingly in a mutually supportive way. Unlike the CBD, the WTO has not yet addressed its relationship with the IU.

The most recent meeting of the CBD Conference of the Parties affirmed that the IU was to "play a crucial role in the implementation of the Convention on Biological Diversity".³⁸ Any analysis of how TRIPS affects the ability of Parties to adhere to obligations under the CBD, must also consider the IU. The successful conclusion of a strongly constructed and binding IU will be one of the most crucial steps that can be taken to ensure the conservation of agricultural biodiversity.

access), then local communities may benefit financially from the use by others of their knowledge and practices. To the extent they do not achieve these goals, existing IPR systems may be changed to make them more easily available to indigenous and local communities to protect and commercialise their resources themselves.

This view is not shared by many others, who believe that the commodification of traditional knowledge is inherently problematic. Some indigenous organisations and others have noted that commercialisation is not always desired, they regard the use of IPRs as culturally inappropriate in some circumstances, and place emphasis on developing non-IPR based solutions as an approach that is more respectful of traditional knowledge.

To protect traditional knowledge, new approaches are required at the national and international levels. At the national level, measures must be developed in light of national priorities, and the needs of indigenous and local communities. A national legislative approach alone cannot ensure that citizens from other countries do not misappropriate the genetic resources of the source countries. At the international level, some minimum framework will be required to protect against misappropriation, and to ensure fair benefit sharing. Participants at a recent discussion sponsored by UNCTAD, for example, noted that no international system has yet been developed to adequately preserve traditional knowledge, protect the rights of knowledge holders, and compensate them equitably for its use.³⁹ To ensure appropriate access and benefit sharing, and to achieve other CBD goals such as preserving traditional knowledge, new *sui generis* systems should be considered.

The development of appropriate *sui generis* systems will depend, at least as far as they provide protection for plant varieties, on the degree of flexibility left to WTO Members when implementing Article 27.3(b). Currently, the TRIPS agreement provides significant flexibility as to what is an “effective” *sui generis* system.⁴⁰ However, there is concern that “UPOV 91” (See Box 3) will be suggested as the benchmark “effective” *sui generis* system. This system limits farmers’ rights, and could disrupt the traditional practice saving and exchanging seed. With the deadline for joining the more flexible 1978 Act having passed, new signatories to UPOV are being pressured to join 1991 Convention. The WTO deadlines for implementation are further increasing this pressure.

Whether existing IPR systems should apply to traditional knowledge remains a controversial question, as does the process by which it is discussed. Discussions of whether and how to protect traditional knowledge – at the CBD and elsewhere – must be driven, not by commercial interests seeking to profit from its use, but by indigenous and local communities themselves. They must also reflect the different circumstances of countries at different levels of development.

c. The TRIPS Agreement may affect the transfer of technology

The IPR systems that WTO Members must implement under the TRIPS Agreement raise two broad sets of issues regarding the technology-related objectives of the CBD:

First, IPRs, including patents and *sui generis* systems for the protection of plant varieties, may have a significant impact on the *types* of technology developed and whether they are appropriate for “the conservation and sustainable use of biological diversity or make use

BOX 3 – The Union for the Protection of New Varieties of Plants (UPOV)

The most recent version of the UPOV system of plant variety protection – “UPOV 91” – is being promoted by some developed countries as the benchmark “effective *sui generis* system” for the purposes of Article 27.3(b) of the TRIPS Agreement.

The UPOV Convention provides a “ready-made” system of plant variety protection, and places a strong emphasis on the rights of plant breeders. UPOV 91 supersedes an earlier version of the Convention, known as UPOV 78. The 1991 Convention has been in force since 1998 and, although many countries believe the 1978 version is more consistent with the interests of developing countries, States wishing to adhere to UPOV are required to conform to the requirements of the 1991 Convention.⁴⁸

While UPOV offers ready-made *sui generis* protection, as well as technical assistance, it is not the only alternative for the implementation of Article 27.3(b). Between the 1978 and 1991 versions, some important changes were made, leaving many developing countries feeling that the current version of UPOV places the rights of plant breeders above other important national priorities. Changes reflected in the 1991 version of UPOV include 1) the explicit inclusion and limitation of the “farmers’ privilege”, and 2) the extension of “plant breeders’ rights”.

“Farmers’ privilege” refers to the right of farmers to save the seeds of protected varieties after harvest for later replanting. In UPOV 91, respect for the farmers’ privilege is placed at the discretion of the implementing State. Many commentators are concerned that this aspect of UPOV 91 seems to make the farmer’s privilege optional, may limit the right of farmers to save and exchange seed, and thus runs counter to the CBD’s goal of promoting the conservation and sustainable use of the components of biological diversity, as well being as inconsistent with the preservation of traditional practices.

UPOV 91 extends “plant breeders’ rights” to cover not merely the protected variety, but also harvested material, and “products made directly from harvested material of the protected variety” (if the variety is used without the breeder’s authorisation). Further, the 1991 Act broadened the scope of coverage to include “essentially derived varieties”, with implications for the ability of breeders and others to use or breed with varieties that are very closely related to,⁴⁹ but are not, the protected variety. These are very significant increases in the rights of seed companies, and are arguably inconsistent with appropriate protection of farmers’ rights over food, and to food security.

In addition, many commentators note that UPOV 91 protects only varieties that are deemed sufficiently “stable” and “uniform”, and thus disregards traditional varieties that preserve greater genetic diversity – adding to plant “hardiness” and reducing the risk of crop failure. The protection and use of uniform varieties, may encourage their use at the expense of locally developed landraces. These landraces are often well suited to the local microclimate, and robust, due to the diversity within the gene pool.⁵⁰ As currently drafted, nothing in UPOV provides an incentive for the maintenance of the diversity found within these landraces.

of genetic resources and do not cause significant damage to the environment”. In this context, technologies contemplated by the CBD include both those resulting directly from the use of genetic resources (e.g. biotechnology), and a broader category of technology

“relevant to” conservation and sustainable use of biodiversity (e.g. agriculture and land-use technologies).

Market-based IPR incentives often promote the development of technology that is focused less towards the needs of poorer communities – to health, food security, and environmentally sound technology – and more towards the interests of private industry in the North. An example of how market incentives may promote the development of potentially inappropriate technologies is what is referred to by industry as “genetic use restriction technologies”. This technology has been used to develop plants that produce sterile seeds (known by its critics as “terminator technology”) or that require a chemical “switch” to be applied before they will exhibit certain characteristics, such as flowering (known as “traitor technology”). There is concern that these technologies, as well as undermining the right of farmers to save and re-use seeds without dependence on corporate seed companies, will threaten biological diversity and the environment. The implications of IPRs on the nature of technologies developed from genetic resources must be further examined.

Second, IPRs may also have a significant effect on *access to and transfer of technology* to developing countries on “fair and most favourable terms” as required by the CBD. The TRIPS Agreement also includes obligations regarding the transfer of technology, including its objectives in Article 7 (which define technology transfer as a fundamental objective of the TRIPS Agreement) and Article 66.2 (which require incentives to be established to encourage technology transfer to the least developed countries). As noted, however, little has been done to implement these provisions, and concern has been raised about the requirements of Article 27.3(b) regarding IPR protection over plants, micro-organisms and micro-biological processes, and the consequent control of the components of biological diversity.

The role of IPRs in technology transfer is complex, and empirical research is limited and largely inconclusive.⁴¹ Some developed countries argue that strong IPRs are necessary to encourage technology transfer and development.⁴² Many developing countries, by contrast, note that investment, innovation and technological development and transfer are more dependent on other factors,⁴³ and IPRs, to the extent that they have an influence, could consolidate control over technology, raise prices, and reduce access. To understand these linkages fully further, detailed research is required. Nevertheless, a preliminary analysis of developments in biodiversity-related industries such as the pharmaceutical and agricultural biotechnology sector - provide cause for concern.

IPR-related control over technology derived from genetic resources is particularly intense in the pharmaceutical and agricultural biotechnology industries. The top ten (10) corporations in the pharmaceutical, seed and agrochemical markets in 1999 accounted for approximately 36, 40 and 82% of the respective global markets.⁴⁴ This industry concentration – and associated consolidation of IPRs – raises serious challenges in both developed and developing countries. It may allow those who gain ownership over genetic resources to raise prices, impose restrictive licensing conditions, restrict ongoing research, and undermine their competitors; all of which may hinder the diffusion of technology. This tendency may be exacerbated by the practice in some countries of granting overly broad biotechnology patents. Patents of extremely broad scope, in some cases covering entire crop species, have been granted to private interests.⁴⁵

Finally, the type of foreign investment in developing countries that is encouraged by IPRs as one of a number of factors, may often not be the type that will most effectively contribute to the development of local infrastructure and technology. Investment may be intra-firm and of an adaptive nature, rather than encouraging original research and development.⁴⁶ In light of these problems, Parties to the CBD should give careful consideration to the role of IPRs in technology transfer contemplated in the CBD. Some suggestions regarding technology transfer are offered in the recommendations section below.

d. The TRIPS Agreement may affect the conservation and sustainable use of biological diversity

In addition to the effects outlined above, the IPRs established pursuant to the TRIPS Agreement may have other effects on the conservation and sustainable use of biological diversity. These impacts on biodiversity conservation are often indirect, and are difficult to measure with precision.

In the area of agriculture, for instance, some argue that IPRs may help conserve biodiversity by providing new economic incentives for its conservation; encouraging the development of new conservation technologies; or promoting more efficient agricultural land use (through, for example, the development of high-yield or crops). Others, by contrast, argue that existing IPR systems, combined with other national policies such as subsidies, encourage the expansion of monocultures based on genetically uniform varieties that displace biologically diverse traditional agricultural systems. They note that IPRs over biotechnological innovations encourage the marketing of fewer varieties and contribute to the removal of varieties from circulation.⁴⁷ Commercial priorities may thus result in the expansion of monocultures at the expense of the more diverse agricultural eco-systems that provide a main storage of *in situ* biological diversity. It has also been noted that new genetically modified varieties – particularly those modified to arrest plant immune systems, or their ability to germinate – may pose a threat of genetic pollution with largely unknown consequences.

Understanding the precise contribution of IPRs to the conservation and sustainable use of biodiversity, when viewed in the light of other policies such as government farm credits and subsidies, will require further exploration. However, to the extent that IPRs are considered essential to the industries involved, and in view of the increasing corporate control of agricultural biotechnological research, their role cannot be underestimated.

4. Recommendations for Action

Policy-makers have an important role to play in ensuring that policies and practices relating to IPRs, and the need for the conservation of biodiversity, are mutually supportive. Governments must adopt an integrated approach across national and international fora, as well as between different international fora, if they are to create space for implementing the objectives and provisions of the CBD.

In addition to taking action at the CBD and the WTO, policy-makers should ensure that work in other international fora is supportive of, and does not undermine, successful resolution of issues relating to IPRs. Relevant institutions include: the UN Food and Agriculture Organisation (FAO);⁵¹ certain UN human rights bodies and instruments;⁵² the United Nations Conference on Trade and Development (UNCTAD);⁵³ the UN Educational, Scientific and Cultural Organisation (UNESCO);⁵⁴ and the World Intellectual Property Organisation (WIPO).⁵⁵ A discussion of each of these organisations is beyond the scope of this paper. Nevertheless, some of the recommendations offered below – both for action and the international and national level – consider the role of other international institutions when seeking to implement CBD objectives.

Below are steps that the Parties to the CBD and Members of the WTO should take at the respective institutions, and at the national level, to ensure that the CBD and TRIPS Agreements work in a mutually supportive way with respect to the four areas of access and benefit sharing, respect for and the preservation of traditional knowledge, technology transfer and the conservation and sustainable use of biological diversity.

a. Action at the International Level

At the international level, both procedural and substantive steps should be taken at both the CBD and the WTO that would enhance the ability of the agreements to be implemented in a mutually supportive way.

Convention on Biological Diversity

To ensure realisation of the CBD's goals, Parties should consider:

- ◆ **Insisting on permanent observer status in the Council for TRIPS.** So far, the WTO has failed to grant the CBD observer status in the TRIPS Council. A recent General Council decision recommended to the TRIPS Council that the CBD be able to observe on an *ad hoc* basis, pending further discussion by the General Council on requirements for observer status in WTO bodies. Given the direct relationship between the work of the CBD, an international body representing over 160 countries, and the TRIPS Council the request for observer status should be granted immediately by the WTO, and on a permanent basis.
- ◆ **Developing strong guidelines for access and benefit sharing.** Parties should consider encouraging the Ad Hoc Open-ended Working Group to develop guidelines that: 1) suggest minimum binding requirements for access and benefit sharing for implementation in national law; 2) emphasise the need to permit in national legislation

a multilateral system of exchange for genetic resources relating to food and agriculture, and other resources as appropriate (See Box 2); and 3) promote other CBD obligations including technology transfer, respect for and preservation of traditional knowledge, and conservation and sustainable use of biological diversity.

- ◆ **Requesting the CBD Secretariat to compile further case studies and empirical evidence.** Further information is required on the relationship between IPRs, the TRIPS Agreement and the CBD in order to inform the work of COP subsidiary bodies including the Panel of Experts and the Ad-hoc Open-ended Working Group. Specifically, Parties should consider:
 - **Providing additional comments on the role of intellectual property in access and benefit sharing.** The COP called for comments on the role of IPRs in access and benefit sharing by the close of 2000 (decision V/26).⁵⁶ Although that time has passed, Parties should consider providing additional case studies on the impact of IPRs on access and benefit sharing, including on cases of IPR-related misappropriation of traditional knowledge. To ensure adequate inclusion of the views of national stakeholders, Parties wishing to comment should consider undertaking national consultations, in particular with indigenous and local community stakeholders.
 - **Compiling experience of the impact of IPRs on technology transfer relevant to the CBD.** Further in-depth research on the implications of IPRs on the transfer of technology relevant to conservation and sustainable use of biological diversity, or that makes use of genetic resources is required. In particular, case studies of where IPRs have affected the transfer of technology on “fair and most favourable terms” would provide the basis for future discussions in the COP. Further analysis of the effect of IPRs on technology transfer of environmentally sound technologies could also be considered.
 - **Compiling further case studies on the impacts of IPRs on the conservation and sustainable use of biodiversity.** Further case studies are required to clarify the relationship between IPRs and the conservation and sustainable use of biological diversity. Among other things, these studies should feed into the Ad Hoc Open-ended Working Group.
- ◆ **Supporting the conclusion of a binding International Undertaking (IU).** CBD parties should consider encouraging the FAO to conclude negotiations for a binding IU and explore the potential for the IU to become a protocol to the CBD. Among other things, the binding IU should: 1) cover access arrangements for all varieties of crops covered by the IU including those on farms, in research institutes, and in public and private collections; 2) ensure that benefit sharing arrangements can apply to resources that are currently privatised; and 3) require recognition of Farmers' Rights. In addition, CBD Parties and IU signatories should adopt a common approach towards the WTO, and seek to ensure that plant genetic resources for food and agriculture – including intact material, germplasm and genes – are exempt from IPRs. Finally, the IU should request observer status in the TRIPS Council and the CBD should support the IU in that request.

The TRIPS Agreement

To ensure that the TRIPS Agreement promotes and does not interfere with the ability of governments to implement their obligations under the CBD, WTO Members should consider:

- ◆ **Granting the CBD permanent observer status in the TRIPS Council.** WTO Members – in the TRIPS Council and General Council – should immediately grant the CBD permanent observer status in the TRIPS Council.
- ◆ **Revising the requirements for patent applications to help prevent misappropriation of knowledge regarding genetic resources and to ensure consistency with access and benefit sharing regimes pursuant to the CBD.** WTO Members should consider revising Article 27.3 (b) or Article 29 of the TRIPS Agreement, “Conditions on Patent Applicants”, to ensure that patent applicants state the country of origin of claimed subject matter, prove rightful access to the knowledge or resource (in line with national law, or in its absence, according to international guidelines). These conditions will also help patent offices establish whether the novelty requirement for the grant of a patent has been met by the applicant.
- ◆ **Extending the period for implementation of Article 27.3(b).** To ensure that Members have sufficient space to undertake and implement the results of a substantive review of Article 27.3(b), WTO Members should agree that the period for implementation be extended until five years after a substantive review of Article 27.3 (b) is completed. A five year period is in line with general transitional periods in the TRIPS Agreement, and is the minimum time in which it is reasonable to expect Members to adopt national systems.
- ◆ **Completing a substantive review of Article 27.3(b), and using the review to harmonise the TRIPS Agreement with the CBD and the International Undertaking.** WTO Members should consider insisting on a review of the substance of Article 27.3(b) of the Agreement. A substantive review can establish whether Article 27.3(b) can operate consistently with CBD obligations, or if it requires amendment. Using the list of issues presented by the Chair at the end of the March meeting of the TRIPS Council will enable each issue to be discussed systematically. The review should ensure that Article 27.3(b) is amended so that it does not frustrate the CBD objectives and provisions, or those of the IU.
- ◆ **Expanding the exceptions to patentability under Article 27.3(b).** Many WTO Members are concerned that a few developed countries may try to force life patenting upon them by urging the removal or narrowing of TRIPS Article 27.3(b) exclusions. At a minimum, these countries should consider insisting on retaining the discretion not to grant plant and animal patents that the current language of Article 27.3(b) allows. They should argue that the exceptions should be expanded to include microbiological processes and essentially biological processes. The discretion to refuse patents over life is essential to give Members who are also CBD Parties the flexibility they need to experiment with approaches for implementing CBD.
- ◆ **Resisting attempts to reduce flexibility in defining *sui generis* systems.** WTO Members should resist attempts to define UPOV 91 as the benchmark “effective *sui*

generis system”. The ability to implement TRIPS consistently with the CBD requires that there be no prescriptive definition of effective *sui generis* system at the international level. The review should consider inserting include a footnote to 27.3(b) to affirm that *sui generis* systems allow Members to implement their obligations under other international agreements, and to protect other economic and social priorities as each Member sees fit.

- ◆ **Undertaking a “sustainability review” under Article 71.1 of the TRIPS Agreement.** The review should ensure that implementation of the TRIPS Agreements supports its objectives, as set out in its preamble and Article 7, as well as the broader objective of the WTO to promote trade “in accordance with the objective of sustainable development”. In the event that the TRIPS Agreement fails to meet these objectives, or is found inconsistent with the successful implementation of international agreements, such as the CBD, WTO Members should consider amending it, as permitted by Article 71.1 and Article X of the WTO Agreement. As required in Article 16(5) of the CBD, Parties must cooperate to ensure that IPRs are supportive of, and “do not run counter” to, the objectives of the CBD.
- ◆ **Avoiding disputes from arising in relation to IPRs, and the provisions of the CBD and the TRIPS Agreement.** To reduce tensions between the TRIPS Agreement and the CBD, WTO Members should consider:
 - **Putting in place a moratorium on unilateral pressure and challenges at the WTO dispute settlement system.** WTO Members should agree to a moratorium on any challenges against developing countries until the reviews under Articles 27.3(b) and 71.1 are complete, and any extended transitional periods are over. Further, WTO Members should refrain from exercising unilateral pressure that aims to have developing countries implement intellectual property regimes that offer a higher level of intellectual property protection than required by the TRIPS Agreement.
 - **Ensuring CBD objectives are taken into consideration in the WTO dispute settlement process.** WTO Members should ensure that dispute panels are aware of, and understand and assist in the enforcement of the obligations of the CBD, by drawing up a list of experts who could sit on panels when disputes involve CBD objectives. This will help protect Members should they be taken to dispute settlement both during and after the transitional period. Taking adequate time to draft CBD consistent TRIPS legislation should be considered by the dispute panel.
 - **Affirming that, in the event of a conflict, the TRIPS Agreement will not interfere with a Party’s legitimate implementation of its CBD obligations.** WTO Members should affirm that in the event of a conflict, the TRIPS Agreement should not interfere with a Party’s legitimate implementation of its CBD obligations.

b. Action at the National Level

The following recommendations suggest ways for governments to utilise flexibility within the CBD and TRIPS Agreement to implement the obligations of both agreements in ways that most effectively support the objectives of the CBD. The recommendations also include other policy measures that could be taken in support of the CBD objectives.

To ensure the achievement of the CBD’s objectives, national policy-makers will need to

adopt integrated approach towards policy-making across sectors that relate to IPRs, the CBD and the TRIPS Agreement. Communication between ministries and departments, and the use of mechanisms to ensure the development of integrated policies, will be required to ensure that the TRIPS Agreement promotes and does not undermine the achievement of the CBD's objectives. Specifically, policy-makers should consider:

- ◆ **Developing and implementing Access and Benefit Sharing Schemes.** These should include minimum binding standards in national legislation.
- ◆ **Developing procedures for prior informed consent.** These procedures should be developed in cooperation with local and indigenous communities.
- ◆ **Defining core intellectual property concepts carefully in national legislation.** For example, what is “novel” or an “invention”, must be carefully defined to ensure that genetic resources are not removed from the public domain. To protect traditional knowledge from misappropriation, patent offices should examine sources such as oral testimony, visual evidence, and material held in gene bank deposits when applying the “novelty” requirement. Careful definition of core concepts will avoid strengthening IPRs further than required by the TRIPS Agreement, and reduce its potential to undermine the CBD.
- ◆ **Using the exclusions to life patenting under Article 27.3(b).** Policy-makers should consider excluding life patenting in order to implement their CBD obligations, including the development of national measures to protect traditional knowledge, and to ensure fair and equitable access and benefit sharing.
- ◆ **Ensuring *sui generis* systems are consistent with CBD obligations.** Governments should utilise the flexibility inherent in the TRIPS Agreement’s requirement for “effective” *sui generis* protection of plant varieties. Effective *sui generis* systems should be consistent with the provisions of the CBD and the IU, protect farmers’ rights, including the right to save and share seeds, and respect national priorities regarding protection of traditional knowledge, and access and benefit sharing.
- ◆ **Recording experiences of TRIPS/CBD tensions or how they have been resolved.** Policy-makers should record any examples of how their obligations under the TRIPS Agreement have affected their ability to fully achieve CBD objectives. These experiences could be shared with other governments and intergovernmental organisations, and could be provided to the CBD in response to their request for comments on the relationship between IPRs and access and benefit sharing.
- ◆ **Ensuring indigenous and traditional local community representatives have full participation in the development of strategies on the preservation and protection of traditional knowledge.** Governments should consider taking steps to ensure that indigenous and traditional local community leaders have full participation in the development of strategy on IPRs and the preservation and protection of traditional knowledge. National delegations to any international forums discussing traditional knowledge should seek to include representatives of indigenous and traditional local communities.

- ◆ **Considering the development of registries of traditional knowledge.** The development of registries of traditional knowledge at the national level or international levels, and the sharing of this information with patent offices throughout the world, may contribute to preventing the misappropriation of traditional knowledge. The inclusion of traditional knowledge in such registries is appropriate only with the prior informed consent of the community in question.
- ◆ **Ensuring that national intellectual property offices are adequately resourced.** To undertake their tasks in a manner that promotes the goals of the CBD, patent offices must be well resourced. They must have sufficient resources to complete a thorough search of "prior art" and to avoid granting overly broad and otherwise inappropriate patents.⁵⁷
- ◆ **Assisting in the articulation Human Rights principles as they relate to IPRs.** Policy-makers should consider assisting the Committee for Economic, Social and Cultural Rights to draft a General Comment on the relationship between economic, social and cultural rights, and IPRs specifically with the provision of case studies illustrating national experiences. Policy-makers should also support the completion of the Draft Declaration on the Rights of Indigenous Peoples, with strong provisions for the control by indigenous people of their cultural and biological resources. Policy-makers should also ensure that IPR systems – including any required by WTO agreements – promote and do not undermine fundamental human rights to self-determination, food, health and development.⁵⁸

Endnotes

1. CONVENTION ON BIOLOGICAL DIVERSITY, June 5, (1992) Article 1 [hereinafter CBD].
2. As noted by the CBD Secretariat “the treatment of IPRs was a contentious issue in the negotiations on the Convention. Many developing countries argued that the application of existing IPR systems hinders the transfer of technology to the developing world, and unfairly disregards the contributions of generations of farmers to the world plant genetic resources, which underpin global food security.... For their part, some developed countries argued that strong universal protection of IPR would stimulate technology transfer and investment in research and development in developing countries, indirectly increasing the incentives to conserve biological diversity.” See *Report of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity*, United Nations Environment Programme, Conference of the Parties to the Convention on Biological Diversity, Doc UNEP/CBD/COP/3/23 at para. 13.
3. THE AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, World Trade Organisation (1995) Article 28 [hereinafter the TRIPS agreement].
4. The scope of intellectual property rights refers to a number of factors such as the subject, duration, category of activities that IPRs extend to, as well as the availability of exceptions to private rights such as compulsory licensing, and other exceptions for research and non-commercial uses.
5. CBD, *supra* note 1, Article 15.
6. See, UNEP, *The Relationship between Intellectual Property Rights and the Relevant Provisions of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Convention on Biological Diversity*. Note by the Executive Secretary, Doc UNEP/CBD/ISOC/5 at para. 5.
7. UNEP, *Panel of Experts on Access and Benefit-Sharing, Options for Access and Benefit-Sharing Arrangements*, Note by the Executive Secretary, 3 September (1999), Doc UNEP/CBD/EP-ABS/2.
8. CBD, *supra* note 1, Article 8(j), See also, decision V/18 of the Conference of the Parties.
9. This approach is also reflected in Article 10(c), which provides that each Party shall encourage the sustainable use of the components of biological diversity by protecting and encouraging “customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements”.
10. US patent N° 5663484.
11. The Times of India Online *India Business*, 24 July (2000) available at <http://www.timesofindia.com/240700/24busi2.htm>
12. Rural Advancement Foundation International (RAFI), *Bio-piracy - Annual Update*, (1996) available at <http://www.rafi.org>.

13. Wisner, Glenn, *PTO Rejection of the "Ayahuasca" Patent Claim*, Center for International Environmental Law (CIEL) (1999) available at www.ciel.org/ptorejection.html. (Noting that the US patent owner planned to establish an Ayahuasca processing plant in Ecuador, where a proposed bilateral intellectual property recognition agreement with the United States may have required those Amazonian people based in Ecuador to recognise the patent).
14. *Id.*
15. *Id.*
16. CBD *supra* note 1, Article 16. See also, Decision V/26A of the Conference of the Parties.
17. UNEP, *supra* note 6 at para. 23.
18. CBD, *supra*, note 1, Article 10.
19. Note that trade secrets and geographical indications may also have some relevance to biodiversity concerns.
20. TRIPS Agreement, *supra* note 3 at Article 65.2.
21. *Id.*, at Article 65.4.
22. *Id.*, at Article 66.1.
23. See, for example, discussion of UPOV in Box 3 and text, also *States Party to the International Convention for the Protection of New Varieties of Plants*, International Union for the Protection of New Varieties of Plants (hereinafter UPOV), Geneva (2000) available at <http://www.upov.int>.
24. TRIPS Agreement, *supra* note 3, at Article 27.1. Note that these requirements establish the terms under which Members *must* offer patent protection. Members are free to offer even broader patent protection if they wish, so long as it does not contravene any other TRIPS provisions, see TRIPS Agreement, *supra* note 3 at Article 1.1.
25. TRIPS Agreement, *supra* note 3, Article 27.3(b).
26. UNEP, *supra* note 6 at paras. 12 and 13.
27. WTO, *Chairman's Statement on Agenda Item 4, Minutes of General Council*, 7 February (2000).
28. UNDERSTANDING ON RULES AND PROCEDURES GOVERNING THE SETTLEMENT OF DISPUTES, World Trade Organisation (1995).
29. It is relevant to note that Article 22(1) of the CBD provides "The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity".
30. *Report of the Fifth meeting of the Conference of the Parties to the Convention on Biological Diversity*. United Nations Environment Programme, Conference of the Parties to the Convention on Biological Diversity (2000) Doc UNEP/CBD/COP/5/23 Decision V/26.
31. For further information on the issues surrounding the protection of traditional

- knowledge, see the proceedings of the U.N Conference on Trade and Development conference titled '*Systems and National Experiences for Protecting Knowledge, Innovation and Practices*' Geneva 30 October-1 November (2000), and the World Intellectual Property Organisation's draft paper on traditional knowledge, *WIPO Draft Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge* (1999), available at <http://www.wipo.org>.
32. *Fifth Intersessional meeting of the Contact Group Rome*, Composite Draft Text Commission on Genetic Resources for Food and Agriculture, International Undertaking on Plant Genetic Resources for Food and Agriculture, 5-10 February (2001) FAO Doc CGRFA/CG-5/01/2 Article 1.1.
 33. Stannard, Clive, *The Relationship between Article 27.3(b) of the WTO TRIPS Agreement and the FAO Undertaking on Plant Genetic Resources*, an address at the South Centre, Istituto Agronomico Oltremare Workshop on TRIPS, The Convention on Biological Diversity and Farmer's Rights, Geneva, June (2000)
 34. ICTSD, *IU Revision Moving Slowly But Steadily*, BRIDGES WEEKLY TRADE NEWS DIGEST. Vol 5, no5 (2001)
 35. FAO Note *Supra* note 32. Article 13.2 (d)
 36. *Id.* Article 14(d)(iv).
 37. *Report of the Second Meeting of the Conference of the Parties to the Convention on Biological Diversity*. United Nations Environment Programme, Conference of the Parties to the Convention on Biological Diversity (1995) Doc UNEP/CBD/2/19 Decision II/15.
 38. UNEP *supra* note 31 annex III.
 39. United Nations Conference for Trade and Development, conference entitled '*Systems and National Experiences for Protecting Knowledge, Innovation and Practices*', Geneva, 30 October - 1 November (2000).
 40. See, UPOV, *States Party to the International Convention for the Protection of New Varieties of Plants* (2000) available at <http://www.upov.int>. The United States has described UPOV 91 as the "effective" *sui generis* system for the purposes of the TRIPS Agreement. There is concern that attempts to define an effective *sui generis* system may reduce the flexibility of Members to design *sui generis* systems that are consistent with their priorities and obligations under other international instruments. See, for example, Delegation of the United States to the Council for TRIPS, *Review of the provisions of Article 27.3(b) – Communication from the United States*, 20 October (1999), Doc IP/C/W/162.
 41. Among other things, it may vary with the technology being licensed, the industries involved, the respective economic power of the IPR holder and user, and other factors.
 42. See, Delegation of the United States to the Council for TRIPS, *Review of the provisions of Article 27.3(b) – Communication from the United States*, 20 October (1999), Doc IP/C/W/162.
 43. For a discussion of the factors affecting technology transfer, see for example, Kumar, Nagesh, *Technology Generation and Technology Transfers in the World Economy*:

Recent Trends and Implications for Developing Countries, INTECH INSTITUTE FOR NEW TECHNOLOGIES, DISCUSSION PAPER SERIES # 9702, The United Nations University (1997). See also, Brenner, Carliene, *Intellectual Property Rights and Technology Transfer in Developing Country Agriculture: Rhetoric and Reality*, Technical paper No. 133 Unclassified, OECD Development Centre, Paris (1998) Doc CD/DOC(98(3); GAIA/GRAIN, *Intellectual Property Rights and Biodiversity: The Economic Myths*, GLOBAL TRADE AND BIODIVERSITY IN CONFLICT Issue 3, October at 2-4 (1998) at 2-4 available at <http://www.grain.org/publications/gtbc/issue3.htm>; United Nations Commission for Trade and Development(UNCTAD), *World Investment Report 1999*, UNCTAD (1999); Barton, John H., *The Impact of Contemporary Patent Law on Plant Biotechnology Research*, address before the OECD Committee on Competition Law and Policy, 23-24 October (1997), in CROP SCIENCE OF AMERICA, INTELLECTUAL PROPERTY RIGHTS III GLOBAL GENETIC RESOURCES: ACCESS AND PROPERTY RIGHTS (1998) at 92-97

44. Rural Advancement Foundation International (RAFI), *The Life Industry*, (1999), available at <http://www.rafi.org>. Concentration in these industries is rapidly becoming even more pronounced, such as with the merger of AstraZeneca and Novartis to form Syngenta (See <http://www.syngenta.com>). This new company, together with Dupont/Pioneer, Monsanto, Aventis and Dow Agrosciences, will hold between 30-50% of all plant biotech patents, and 70% of the global agrochemical market. See, Warwick, H., *Syngenta: Switching off farmers right?*, EVB, ActionAid, GeneWatchUK, Swedish Society for Nature Conservation (2000).
45. Calgene, for example, received a U.S. patent awarding it rights over all genetically engineered brassicas, which include broccoli, cauliflower and cabbage. Similarly, Monsanto owns a patent on all genetically engineered varieties of the cotton that constitutes over 90% of the world cotton output. See Barton, John H., *The Impact of Contemporary Patent Law on Plant Biotechnology Research*, address before the OECD Committee on Competition Law and Policy, 23-24 October (1997), in CROP SCIENCE OF AMERICA, INTELLECTUAL PROPERTY RIGHTS III GLOBAL GENETIC RESOURCES: ACCESS AND PROPERTY RIGHTS (1998) at 92-97. In addition, concern has been expressed that the rush to map genomes will result in the entire genome of certain staple food crops being owned by single corporations. Recently, Syngenta, the world's largest agribusiness company, announced it had sequenced the entire genome of rice. Already, it is clear the information will only be available through contracts. See Action Aid, *CROPS AND ROBBERS, BIOPIRACY AND THE PATENTING OF STAPLE FOOD CROPS*, (1999), Dickson,D., and Cyranowski,D., *Commercial Sector scores success with whole rice genome*, NATURE BIOTECHNOLOGY Vol 409 1 February (2001) at 551.
46. See Kumar, Nagesh, *Technology Generation and Technology Transfers in the World Economy: Recent Trends and Implications for Developing Countries*, INTECH INSTITUTE FOR NEW TECHNOLOGIES, DISCUSSION PAPER SERIES # 9702 The United

Nations University (1997), Also Brenner, Carliene, *Intellectual Property Rights and Technology Transfer in Developing Country Agriculture: Rhetoric and Reality*, Technical paper No. 133 Unclassified, OECD Development Centre Paris (1998) Doc CD/DOC(98(3) and GAIA/GRAIN, *Intellectual Property Rights and Biodiversity: The Economic Myths*, GLOBAL TRADE AND BIODIVERSITY IN CONFLICT Issue 3, October (1998) at 2-4 available at <http://www.grain.org/publications/gtbc/issue3.htm>, United Nations Commission for Trade and Development(UNCTAD), *World Investment Report (1999)*.

47. One large seed company, for example, recently declared it would "eliminate 2000 varieties from its product line" See RAFI, *Earmarked for Extinction? Seminis eliminates 2000 varieties*,(2000) available at <http://www.rafi.org>.
48. INTERNATIONAL CONVENTION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS, December 2 (1961) as Revised at Geneva on November 10 (1972), on October 23 (1978) and March 19 (1991).
49. *Id* Article 14(5).
50. Dutfield,Graham, INTELLECTUAL PROPERTY RIGHTS, TRADE AND BIODIVERSITY, IUCN the World Conservation Union/Earthscan (2000) at 50.
51. The importance of the FAO, and a multilateral system of exchange for genetic resources for food and agriculture, is discussed in Box 2.
52. These include the Sub-Commission on the Promotion and Protection of Human Rights, the Working Group on Indigenous Populations (WGIP), the Draft Declaration on the Rights of Indigenous Peoples, and the United Nations Committee on Economic, Social and Cultural Rights. These Human Rights bodies have mandates that are being used to define how human rights principles and intellectual property relate. For example, the Sub-Commission for the Promotion and Protection of Human Rights passed a resolution in August 2000 that, among other statements and requests, requested the High Commissioner for Human Rights to undertake analysis of the human rights impact of the TRIPS Agreement. In November 2000, the Committee for Economic, Social and Cultural Rights held a day of discussion on intellectual property and human rights.
53. UNCTAD is a political and analytical forum to facilitate the discussion of economic issues from a development perspective. UNCTAD recently convened a conference on the protection of traditional knowledge. Also, UNCTAD runs the Biotrade Initiative seeks to assist developing countries to "develop, at the national level, an institutional environment to facilitate trade and investment, in products and services of biological diversity, as a means to attain the objectives of the CBD". See UNCTAD, *Building a new partnership*, Transcript of presentation given to workshop on Access to Genetic Resources and Benefit Sharing, Berne, 13-14 April (2000) at 2.
54. UNESCO has addressed traditional knowledge and intellectual property to the extent of developing model provisions on the protection of folklore.
55. WIPO administers a number of international treaties on intellectual property rights, and has studied and collected case studies on the protection of traditional knowledge.
56. UNEP *supra* note 30, Annex III Decision V26.
57. Even in some developed countries patent offices are not well enough resourced to ensure that this occurs. See Barton, John H., *Reforming the Patent System*, Policy Forum on Intellectual Property Rights, 287 SCIENCE Mar. (2000) at 1933.

58. Article 29 of the Draft Declaration on the Rights of Indigenous People currently states "Indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property. They have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs and visual and performing arts". Policy-makers should ensure that this and related provisions are retained in the Draft Declaration.



The Center for International Environmental Law (CIEL) is a non-profit organization founded in 1989 to promote sustainable development and protect the global environment through strengthening international environmental law and policy.

With offices in Washington D.C. and Geneva, CIEL works with non-governmental organizations, governments, and international agencies to promote sustainable societies, to incorporate fundamental principles of ecology and justice into law, and to inform and train public interest environmental lawyers.

In addition to reforming international trade institutions, CIEL program areas aim at conserving biological diversity, preventing climate change, protecting the rights of individuals and community, reforming international financial institutions, and building capacity for public interest law.

WWF is one of the world's largest and most experienced independent conservation organizations with over 4.7 million supporters and a global network active in 96 countries

WWF's mission is to stop the degradation of the planet's natural environment and to build a future in which humans live in harmony with nature, by:

- Conserving the world's biological diversity
- Ensuring that the use of renewable natural resources is sustainable
- Promoting the reduction of pollution and wasteful consumption



CIEL

160a Rte de Florissant
1231 Conches
Switzerland

Tel: +41 22 789 07 38
Fax: +41 22 789 05 00
www.ciel.org

WWF International

Ave du Mont-Blanc
1196 Gland
Switzerland

Tel: +41 22 364 9111
Fax: +41 22 364 0640
www.panda.org