

Access, Benefit Sharing and Prior Informed Consent

LEGAL MECHANISMS IN SOUTH ASIA



CBD, ITPGRFA and TRIPS

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Acronyms

ABS	:	Access and Benefit Sharing
BCAP	:	Biodiversity Conservation Action Plan
BMCs	:	Biodiversity Management Committees
CBD	:	Convention on Biological Diversity
CPs	:	Contracting Parties
DDC	:	District Development Committee
EDVs	:	Essentially Derived Varieties
EIA	:	Environment Impact Assessment
EU	:	European Union
FAO	:	Food and Agriculture Organisation
GATT	:	General Agreement on Tariffs and Trade
GMOs	;	Genetically Modified Organisms
IGC	:	Intergovernmental Committee
IPRs	:	Intellectual Property Rights
ITPGRFA	:	International Treaty on Plant Genetic Resources for Food and Agriculture
LDCs	:	Least Developed Countries
MFN	:	Most Favoured Nation
MNCs	:	Multinational Companies
NBA	:	National Biodiversity Authority
NGOs	:	Non-governmental Organisations
NPVDF	:	National Plant Variety Development Fund

PGRs	:	Plant Genetic Resources
PIC	:	Prior Informed Consent
PVFRA	:	Plant Varieties and Farmers' Rights Authority
PVP	:	Plant Variety Protection
PVPA	:	Plant Variety Protection Authority
SAARC	:	South Asian Association for Regional Cooperation
SBBs	:	State Biodiversity Boards
TK	:	Traditional Knowledge
TRIPS	:	Agreement on Trade Related Aspects of Intellectual Property Rights
US	:	United States
VDC	:	Village Development Committee
WIPO	:	World Intellectual Property Organisation
WSSD	:	World Summit on Sustainable Development
WTO	:	World Trade Organisation

Foreword

Conservation and sustainable use of biodiversity are a concern for biodiversity-rich regions like South Asia not least because biodiversity in these regions is intrinsically associated with people's livelihood, health, food security, etc. The application of biotechnology over biological resources is growing rapidly across the globe. It is often argued that without the application of biotechnology over biological resources, it would be difficult to address the world's greatest challenges such as poverty, food insecurity and health risks. However, such applications of biotechnology are not without problems, mainly for biodiversity-rich regions. The most complex problems arise from the intellectual property right (IPR) regime under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organisation (WTO).

On the issues of biopiracy and misappropriation of traditional knowledge (TK); and systems of protection provided to commercial seed companies and plant breeders at the cost of community rights, for example, no obligations for fair and equitable sharing of benefits arising out of the utilisation of biological resources and associated TK, the divide is clear between the technology-rich developed countries and biodiversity-rich developing countries.

This publication highlights the major issues on which there is a divergence between developed and developing countries. The report also presents a brief description of the South Asian common position on the review of TRIPS Article 27.3(b), which has become the most controversial issue within the WTO system, mainly because of its provisions on patent and plant variety protection (PVP). An analysis of the features of the Convention on Biological Diversity (CBD), 1992, and International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), 2001 has also been presented. These are the two major international legal instruments that call for the protection of community rights and implementation of access and benefit sharing mechanism at the national

level. The report also presents the status of legal mechanisms on access and benefit sharing in five South Asian countries – Bangladesh, India, Nepal, Pakistan and Sri Lanka.

The publication is a part of the regional programme titled “Securing Farmers’ Rights to Livelihood in the Hindu-Kush Himalayan (HKH) Region”, which SAWTEE, along with its partner organisations, has been implementing in five South Asian countries since 2001. I would like to thank our partners – Bangladesh Environmental Lawyers’ Association (BELA), Bangladesh; Cosumer Unity & Trust Society (CUTS), India; Forum for Protection of Public Interest (Pro Public), Nepal; Sustainable Development Policy Institute (SDPI), Pakistan; and Law & Society Trust (LST), Sri Lanka for providing us the information and reports on the status of legal mechanisms on access and benefit sharing in their respective countries.

This publication has been prepared and edited by Mr Kamalesh Adhikari, Senior Programme Officer of SAWTEE. His efforts in publishing this book, despite all odds, are commendable. Similarly, I would like to thank Mr Navin Dahal, Executive Director, SAWTEE for his inputs and comments. I would also like to extend my thanks to Mr Puspa Sharma, Programme Officer, Pro Public for his comments and suggestions on the text of the publication as well as for his editorial assistance. I would also like to thank Mr Indra Shrestha for preparing the cover design and Mr KamSingh Chepang for designing the internal pages. I would like to express my sincere gratitude to Oxfam (Novib), The Netherlands and Ford Foundation, New Delhi for their financial support in implementing the farmers’ rights programme.

We would like to encourage the readers to provide us comments and suggestions on the contents of this report and help us improve it further in the possible second edition of the same.

Posh Raj Pandey, Ph.D
President, Executive Committee
SAWTEE

Kathmandu
2 July 2006

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Chapter

1

International Legal Instruments on ABS and PIC and South Asia

1. Introduction

1.1. South Asia and biodiversity

South Asia occupies 3.3 percent of the world's land area but is endowed with rich biodiversity. Two of the 12 mega-biodiversity centers of the world are situated in this region and it has more than 15,000 endemic species of plants. The region is also the primary and secondary centers of diversity for many crop plants and owns large genetic diversity in these crops as well as in few more crops introduced from elsewhere. Unlike in other major biodiversity-rich regions, the extent of extinction of species and genetic diversity is relatively less in South Asia though there is a huge population pressure. This region has two of the 34 biodiversity hotspots of the world, where at least 70 percent of the primary, native vegetation is lost (See Ravi 2005a).

The region is also characterised by high dependence on agriculture and related activities for the livelihood of 50 percent to 90 percent of the population. Agriculture contributes a significant share to the gross domestic product of the South Asian economies. There is no other region in the world where biodiversity has such a close linkage with people's livelihood. Not only biodiversity is intrinsically associated with the way of life of peoples, it has also contributed to the evolution of rich traditional knowledge (TK) on the conservation and sustainable use of

biological resources. The region is, however, weak in technological capability, more so in the frontier areas of science. It is one of the main reasons that South Asian countries have not been able to turn their biological resources and knowledge wealth into economic strength. Had they been able to develop required technological capability, there is no denying that they would have been able to use biodiversity as a means to address widespread hunger and rampant poverty (See Ravi 2005b).

1.2. Conservation and sustainable use of biodiversity and associated TK

It is a very widely held belief that conservation and sustainable use of biodiversity do not mean keeping the biological resources and associated TK away from the world. The application of biotechnology over biological resources is growing rapidly across the globe. The proponents of biotechnology argue that without the application of technologies over biological resources, the world would gain nothing but food insecurity, health risks and poverty. However, the opponents argue that biotechnology also possesses complex problems. The most complex problems concern with biopiracy and misappropriation of TK, systems of protection (such as intellectual property rights – IPRs), protection of community rights, and means of fair and equitable sharing of benefits arising out of the utilisation of biological resources and associated TK.

In this context, in order to serve the mutual interest arising from the commercial use of biological resources and TK, the access and benefit sharing (ABS) mechanism, which also ensures prior informed consent (PIC) of the concerned communities and farmers, has been seen as a trade off between the technologically-strong North and the biodiversity-rich South.

2. ABS, PIC and international instruments

There are two important international instruments that deal with ABS and PIC. The first is the Convention on Biological Diversity (CBD), 1992 and the second is the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), 2001. Since IPRs have also gained prominence in the course of the

application of biotechnology over biological resources, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organisation (WTO) should not be overlooked while dealing with the issues of ABS and PIC. In the context of IPRs, and biological resources and associated TK, World Intellectual Property Organisation (WIPO)¹ also holds relevance.

2.1. Convention on Biological Diversity

CBD was adopted on 5 June 1992 at the United Nations Conference on Environment and Development² at Rio de Janeiro, Brazil. This legally binding convention came into force on 29 December 1993. Currently, 188 countries are Contracting Parties (CPs) to CBD. ABS and PIC have been adequately recognised and legitimised in CBD. “Fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over these resources and to technologies, and by appropriate funding” has been set out as one of the three overriding objectives of CBD.³

Article 15 of CBD provides a framework for the implementation of ABS. In recognition of the sovereign rights of the state over their biological resources, national governments, subject to their national laws, are conferred the authority to determine access to genetic resources. Parties are required to create conditions, subject to allowed safeguards, to facilitate access to genetic resources for environmentally sound uses by other CPs.

Access to genetic resources, where agreed, shall be on mutually agreed terms and also on PIC of the CP providing the access. The Providing Contracting Parties and Accessing Contracting Parties are required to establish legal, administrative

¹ This report only provides a brief overview of WIPO and does not deal with recent developments under it.

² In this conference, 157 countries had participated.

³ Article 1 of CBD sets out the three objectives: the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising out of the utilisation of genetic resources.

and policy measures on mutually agreed terms to achieve fair and equitable sharing of the technological benefits arising from research and developments and the economic benefits arising from the commercial utilisation of genetic resources.

Article 8(j) provides for equitable sharing of benefits arising from the utilisation of knowledge, innovations and practices of indigenous and local communities embodying traditional life styles relevant for conservation and sustainable use of biological diversity. Access to such knowledge, subject to national laws, has to be with the approval and involvement of the holders of such knowledge. Under CBD, benefit sharing involves technology transfer⁴, information exchange⁵, technical and scientific cooperation⁶, capability building in science and technology, including biotechnology for distributive benefits⁷ and financial resources and mechanism⁸.

The ABS mechanism under CBD is, indeed, a legitimate entitlement to the communities for rewarding and promoting their role in conservation and sustainable use of biological resources and associated TK. This is also important to facilitate access to the genetic resources and associated TK in the new paradigm set by sovereign rights of countries over their biological resources and associated TK⁹, and IPRs on “living forms” and “processes”¹⁰ (Ravi 2005a).

Developing countries, including South Asian countries, have chosen to devise a national ABS law under CBD. Many of them have already devised and imple-

⁴ Article 16 of CBD deals with access to and transfer of technology.

⁵ Article 17 of CBD deals with exchange of information from publicly available sources.

⁶ Article 18 of CBD deals with technical and scientific cooperation between Contracting Parties.

⁷ Article 19 of CBD deals with handling of biotechnology and distribution of its benefits.

⁸ Articles 20 and 21 of CBD deal with financial resources and financial mechanism.

⁹ Departing from the long held “common heritage of humankind” concept on biodiversity, Articles 3 and 15 of CBD conferred sovereign rights to Contracting Parties over their biodiversity.

¹⁰ The TRIPS Agreement of the WTO requires Members to respect and grant IPR on living forms such as micro-organisms, plant varieties, and microbiological and non-biological processes.

Table 1: CBD and South Asian countries

Countries	Signed	Ratified
Bangladesh	5 June 1992	3 May 1994
Bhutan	11 June 1992	25 August 1995
India	5 June 1992	18 February 1994
Pakistan	5 June 1992	26 July 1994
Nepal	12 June 1992	23 November 1993
Maldives	12 June 1992	9 November 1992
Sri Lanka	10 June 1992	23 March 1994

mented such a law whereas many others are in the process of devising and implementing it. As mentioned above, they view that this would not only provide them a legal basis to regulate access to their resources and associated TK and protect community rights through the ABS mechanism, but would also help them prevent biopiracy and misappropriation of the TK of the communities.

2.2. International Treaty on Plant Genetic Resources for Food and Agriculture

ITPGRFA came into being in November 2001. After more than 15 sessions of the United Nations Food and Agriculture Organisation (FAO) Committee on Genetic Resources and its subsidiary bodies, ITPGRFA was approved during the FAO conference in 2001. The Treaty was purposively introduced to harmonise the International Undertaking on Plant Genetic Resources (IUPGR) signed in 1983 with CBD.

This legally binding Treaty covers only plant genetic resources for food and agriculture (PGRFA). But it does not cover other plant genetic resources (PGRs), like those of medicinal and aromatic uses. It sets up a multilateral system of ABS, and the application of the Treaty provisions is limited to 64 listed PGRs – food and forages – that, according to FAO, are fundamental to food security and are either in the public domain or are under the hold of natural and legal persons.

It is, therefore, the Treaty is critical in ensuring the continued availability of PGRFA that countries need to feed people and guarantee food security at the national and global levels. The general provisions of ITPGRFA require Members to survey, prepare an inventory, and otherwise conserve PGRFA, and to take policy and legal measures to promote their sustainable use. Members also agree to promote the provision of technical assistance to one another, especially to developing country and transition economy Members.

The Treaty has recognised the contributions of farmers in conserving, improving and making available PGRs for sustainable agriculture and food security and has recognised farmers' rights to benefit from such contribution through a multilateral system. Farmers, their contribution and corresponding rights have found place in the ITPGRFA right from the preamble.

The Treaty has recognised the role of farmers as custodians of the PGRs. It has exclusively recognised their rights to save, use, exchange and sell farm-saved seed/propagating material. In addition, the Treaty also provisions for three other sets of farmers' rights. These include:

- protection of TK relevant to PGRs;
- right to equitably participate in sharing benefits arising from the utilisation of PGRs; and
- right to participate in making decisions on matters related to conservation and sustainable use of PGRs.

The Treaty states, "...in accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights...". In addition to it, the provisions of the Treaty on general obligations and financial resources also refer to farmers.

The Treaty was opened for signature until 4 November 2002 by all member states of the FAO or any state who is not a member of FAO, but of the United Nations or any of its specialised agencies or of the International Atomic Energy Agency. The Treaty came into force on 29 June 2004.

Table 2: ITPGRFA and South Asian countries		
Countries	Signed/Acceded	Ratified
Bangladesh	17 October 2002	14 November 2003
Bhutan	10 June 2002	2 September 2003
India	10 June 2002	10 June 2002
Pakistan	Acceded on 2 September 2003	
Nepal	Yet to act on the Treaty	
Maldives	Acceded on 2 March 2004	
Sri Lanka	Yet to act on the Treaty	

Of the seven South Asian Countries, only Bangladesh, India and Bhutan have signed and ratified the Treaty. While Pakistan and the Maldives have acceded to the Treaty, Nepal and Sri Lanka have not yet acted on it.

2.3. Agreement on Trade Related Aspects of Intellectual Property Rights

TRIPS came into being on 1 January 1995. It is the most comprehensive multi-lateral agreement on intellectual property and is a minimum standards agreement, which allows Members to provide more extensive protection of intellectual property if they so wish. Members are left free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice. TRIPS, however, provides for certain basic principles, such as national treatment and most favoured nation (MFN) treatment, and some general rules to ensure that procedural difficulties in acquiring or maintaining IPRs do not nullify the substantive benefits that should flow from the Agreement. The areas of intellectual property that it covers are: copyright and related rights (i.e. the rights of performers, producers of sound recordings and broadcasting organisations); trademarks including service marks; geographical indications including appellations of origin; industrial designs; patents including the protection of new varieties of plants; the layout-designs of integrated circuits; and undisclosed information including trade secrets and test data (www.wto.org).

TRIPS requires all WTO Members to comply with its provisions and harmonise their IPR rules in line with them. As per TRIPS, IPRs are the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time. IPRs are customarily divided into two main areas: Copyright and rights related to copyright; and industrial property (www.wto.org).

Among the industrial property rights, two forms of IPRs directly concern with ABS and PIC – patent and plant variety protection (PVP). Particularly, due to these two forms of IPRs, TRIPS is considered the most controversial agreement of the WTO. Among its various provisions, Article 27.3(b) – since it provisions for patent protection and PVP (*Box 1*) – has engendered considerable debate on the social, economic and environmental implications of strengthened intellectual property protection, mainly in biodiversity-rich developing countries.

Box 1: Patent and PVP

Patent and PVP are the two important forms of IPRs under TRIPS. Both provide exclusive monopoly rights over a creation for commercial purposes over a period of time. A patent is a right granted to an inventor to prevent all others from making, using, and/or selling the patented invention for 20 years and can be obtained for a product as well as a process. The criteria for a patent are novelty, inventiveness (non-obviousness), and utility. The provision for patenting on life form is the most contentious issue within TRIPS. In the case of PVP, it provides patent like rights to plant breeders, for example, for the genetic makeup of a specific plant variety. The criteria for PVP are: novelty, distinctness, uniformity, and stability. The PVP system can provide exemptions to breeders, allowing them to use protected varieties for further breeding, and to farmers, allowing them to save, exchange, reuse and sell seeds. The PVP system is considered the weaker sister of patenting, mainly because of these exemptions. Yet, often touted as a 'soft' kind of patent regime, PVP can be as threatening as industrial patents on biodiversity.

Adapted from: Kuyek, Devlin. 2002. *Intellectual Property Rights in African Agriculture: Implications for Small Farmers*. Barcelona: GRAIN.

It is often argued that Article 27.3(b) has completely undermined the equity principles of ABS and PIC, which are recognised and legitimised by CBD. Biodiversity-rich developing countries view that the Article has not only facilitated unfair exploitation of biological and genetic resources, biopiracy and misappropriation of TK, but has also restricted the rights of the communities and farmers, posing threats over their livelihood options.

It has been perceived that the Article, through the unfair patent provision, has provided a room for the multinational seed companies and commercial plant breeders to unduly utilise the biological resources and associated TK but the communities and farmers, the custodians of such resources and TK, have not been assured a fair and equitable share of benefits that such companies and breeders derive from the commercial use of their resources and TK.

Countries	Membership ¹¹
Bangladesh	Member since 1995
Bhutan	In the accession process
India	Member since 1995
Pakistan	Member since 1995
Nepal	Member since April 2004
Maldives	Member since 1995
Sri Lanka	Member since 1995

Since TRIPS requires WTO Members to implement the agreement by enacting laws at the national level, the South Asian countries, which are Members of the WTO, too need to implement the agreement as per its provisions and their commitment as WTO Members. Except Bhutan, all South Asian countries are WTO Members.

¹¹ Bangladesh, India, Pakistan and Sri Lanka became WTO Members by virtue of being the Members of the GATT, 1947. The Uruguay Round of multilateral trade negotiations had converted the GATT into the WTO in January 1995.

2.4. World Intellectual Property Organisation

WIPO was established by a convention of 14 July 1967, which entered into force in 1970. It has been a specialised agency of the United Nations since 1974, and administers a number of international unions or treaties in the area of intellectual property, such as the Paris¹² and Berne¹³ Conventions. WIPO's objectives are to promote intellectual property protection throughout the world through cooperation among states and, where appropriate, in collaboration with any other international organisation.

WIPO also aims to ensure administrative cooperation among the intellectual property unions created by the Paris and Berne Conventions and sub-treaties concluded by the members of the Paris Union. It is to be noted that the TRIPS Agreement also requires WTO Members to comply with the substantive obligations of the main conventions of WIPO – the Paris Convention on industrial property, and the Berne Convention on copyright (in their most recent versions).

With regard to cooperation on intellectual property issues, there has been an agreement between WIPO and the WTO, which came into force on 1 January 1996. The agreement provides cooperation in three main areas: notification of, access to and translation of national laws and regulations; implementation of procedures for the protection of national emblems; and technical cooperation (www.wto.org).

The WIPO Intergovernmental Committee (IGC) has dealt with a range of issues concerning the interplay between intellectual property and genetic resources. The work of the IGC covers three main areas:

¹² The Paris Convention deals with the protection of industrial property rights and came into being in 1883.

¹³ The Berne Convention deals with rights concerning artistic and literary works and came into being in 1886.

- Defensive protection of genetic resources through measures, which prevent the grant of patents over genetic resources that do not fulfill the requirements of novelty and non-obviousness.
- Intellectual property aspects of access to genetic resources and equitable benefit sharing arrangements that govern use of genetic resources.
- Disclosure requirements in patent applications that relate to genetic resources and associated TK used in a claimed invention (www.wipo.int).

Similarly, WIPO also provides a forum for international policy debate and development of legal mechanisms and practical tools concerning the protection of TK and traditional cultural expressions (folklore) against misappropriation and misuse, and the intellectual property aspects of ABS in genetic resources (www.wipo.int).

3. TRIPS review and recent developments

The TRIPS Agreement requires a review¹⁴ of Article 27.3(b)¹⁵ four years after the implementation of the agreement. However, during negotiations for the review of the Article, Members seemed indifferent to each other's positions, particularly with regard to patents on life forms. Members also seemed to be divided over the issue of IPRs and the rights of breeders and farmers. Developing countries lobbied for the incorporation of CBD principles within TRIPS, but the developed Members, mainly the US and Japan, opposed it. This issue received attention at the Fourth WTO Ministerial in Doha in 2001.

¹⁴ The Article had been subjected for review four years after the implementation of the Agreement, i.e., 1999.

¹⁵ Members may exclude “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.”

Paragraph 19 of the Doha Declaration¹⁶ stipulates that the TRIPS Council should also look at the relationship between TRIPS and CBD and at the protection of TK and folklore (www.wto.org). The Doha Declaration has instructed the Council for TRIPS to examine, *inter alia*, the relationship between TRIPS and CBD; the protection of TK and folklore; and other relevant new developments raised by Members pursuant to Article 71.1¹⁷. The Doha Declaration also stipulated that while undertaking this work, the Council for TRIPS shall be guided by the objectives and principles set out in Articles 7¹⁸ and 8¹⁹ of TRIPS and shall take into account the development dimension.

Most recently discussed are proposals on disclosing the source of biological material and associated TK. The discussion in the TRIPS Council has gone into considerable detail with a number of ideas and proposals for dealing with these complex subjects (*Box 2*).

¹⁶ This Declaration was adopted by WTO Members during the Fourth WTO Ministerial held in Doha in 2001.

¹⁷ The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.

¹⁸ The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

¹⁹ 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Box 2: The present debate on TRIPS review

During the ongoing negotiations for the review of TRIPS Article 27.3(b), the ideas put forward by different countries and groups of countries include:

- Disclosure as a TRIPS obligation: A group represented by Brazil and India, including Bolivia, Colombia, Cuba, Dominican Republic, Ecuador, Peru, Thailand, and supported by the African group and some other developing countries, has proposed to amend TRIPS so that patent applicants are required to disclose the country of origin of genetic resources and TK used in the inventions, evidence that they received PIC, and evidence of fair and equitable benefit sharing.
- Disclosure through WIPO: Switzerland has proposed an amendment to the regulations of WIPO's Patent Cooperation Treaty (and, by reference, WIPO's Patent Law Treaty) so that domestic laws may ask inventors to disclose the source of genetic resources and TK when they apply for patents. Failure to meet the requirement could hold up a patent being granted or, when done with fraudulent intent, could entail a granted patent being invalidated.
- Disclosure, but outside patent law: The EU's position includes a proposal to examine a requirement that all patent applicants disclose the source or origin of genetic material, with legal consequences of not meeting this requirement lying outside the scope of patent law.
- Use of national legislation, including contracts rather than a disclosure obligation: The US has argued that the CBD's objectives on access to genetic resources, and on benefit sharing, could best be achieved through national legislation and contractual arrangements based on the legislation, which could include commitments on disclosing of any commercial application of genetic resources or TK.

Adapted from www.wto.org

Broadly speaking, the review of Article 27.3(b) is still under negotiations with persistent divergence among Members, particularly on the issue of relationship

between TRIPS and CBD. While developed Members have been demanding stronger IPR protections in all fields of technology, including biotechnology, developing and least developed Members have been asking for the amendment of Article 27.3(b) with conditions on patentability such as disclosure of the source of genetic material and TK, and evidence of fair and equitable benefit sharing and PIC.

It is, indeed, clear from the submissions made by the developed Members that they are not yet willing to show flexibilities to fully incorporate the ABS, PIC and disclosure requirement into the ambit of TRIPS.

4. South Asia and approaches to ensure ABS and PIC

4.1. Common position on the Review of Article 27.3(b)

Given the persistent divergence among developed and developing Members on the review of Article 27.3(b), and submissions of different proposals by Members, individually and through groups, South Asian countries should also put forward their regional position on how the Article should be amended. Moreover, since all the South Asian countries have signed and ratified CBD and most of them have already signed and ratified ITPGRFA, with their commitments to implement them at the national level, it would be in their interest to develop a common position on the review of Article 27.3(b), considering the objectives and the implementation aspects of CBD and ITPGRFA.

Is such a common position foreseeable in the case of South Asia? If we observe the common positions made by the LDCs and the developing countries, we find that most South Asian countries have a similar position on the issue (*Box 3*). Hence, there should not be any disagreement among South Asian governments on what should be their common position on TRIPS review. In fact, at a time, when they are making all possible efforts to devise laws under CBD, ITPGRFA and TRIPS itself and implement them at the national level, it is crucial that they capitalise on the South Asian Association for Regional Cooperation (SAARC) forum and put forward their position on TRIPS review through that forum.

Box 3: Positions of the LDCs and developing countries

LDCs' position: The LDC group²⁰ views that the review of Article 27.3(b) should incorporate the conditions on patentability to disclose the source of genetic material and relevant TK. If we look at the past negotiations for TRIPS review and submission of proposals by different LDCs, we find that most LDCs want the evidence of fair, sustainable and equitable benefit sharing, and PIC as a condition for patentability in order to stop biopiracy of genetic resources and TK. Also, the Dhaka Declaration – adopted at the International Civil Society Forum for Advancing LDC Interests in the Sixth WTO Ministerial in the Context of the Doha Development Round, held from 3-5 October 2005 in Bangladesh – had demanded for the incorporation of ABS, PIC and disclosure requirement within TRIPS in the same manner. However, the Sixth Ministerial in Hong Kong did not address these concerns of the LDCs and it is not a surprise that their concerns are still far from being addressed.

Developing countries' position: Prior to the Sixth WTO Ministerial in Hong Kong in December 2005, Commerce Minister of India, Mr Kamal Nath wrote a letter to 31 trade ministers to support the proposal submitted by eight countries²¹ to the TRIPS Council. The proposal urges WTO Members to ensure that TRIPS provisions do not conflict with CBD. The proposal also calls upon WTO Members to ensure that TRIPS duly recognises and respects the spirit of ABS and PIC. In addition, the proposal asks WTO Members to ensure that disclosure requirement be enforced within TRIPS and be made mandatory for the patent applicant to comply with. However, these issues were relegated to backburner at Hong Kong as in the past.

Adapted from the LDC Dhaka Declaration 2003 and www.wto.org

²⁰ The LDC group includes four South Asian LDCs – Bangladesh, Bhutan, the Maldives and Nepal.

²¹ These eight countries are Bolivia, Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand and Venezuela. Out of these, India and Pakistan are the two South Asian developing countries.

4.2. Legislative efforts under CBD, ITPGRFA and TRIPS

Most South Asian governments have been making various legislative efforts to fulfill their commitments under CBD, ITPGRFA and TRIPS. While some of them have already enacted some of the required legislation under these international instruments, others are in the process of enacting them. Therefore, the status of such legislation in select South Asian countries – Bangladesh, India, Nepal, Pakistan and Sri Lanka – has been discussed in the next section.

Chapter

2

Legal Mechanisms on ABS and PIC in five South Asian countries

1. Legal mechanisms in Bangladesh

1.1. Country status

Bangladesh signed CBD on 5 June 1992 and ratified it on 3 May 1994. Similarly, it signed ITPGRFA on 17 October 2002 and ratified it on 14 November 2003. And by virtue of being a GATT Member, the country became a WTO Member in 1995. Domestic preparations to devise national laws to implement CBD and ITPGRFA are underway. As an LDC Member of the WTO, the country has to implement the TRIPS Agreement by 2013²².

1.2. Status of ABS and related laws

In order to comply with CBD and TRIPS, there have been various legislative efforts in Bangladesh. The draft laws on biodiversity protection and PVP are pending for approval. Two different committees constituted by the Ministry of Agriculture prepared these drafts. While the first Committee submitted two sepa-

²² LDC Members have been given an extension until 1 July 2013 to provide protection for trademarks, copyright, patents and other intellectual property, following a decision reached by Member governments on 29 November 2005.

rate but inter-linked drafts on Biodiversity and Community Knowledge Protection Act and Plant Varieties Act of Bangladesh in 1998, the second Committee submitted another draft on Plant Variety Protection in 2003. The draft on biodiversity, which has been prepared keeping in consideration the principles of CBD, deals with sustainable use and promotion of biodiversity and protection of community knowledge, collective innovation and community rights. The drafts on PVP deal with protection of newly innovated plant varieties.

1.2.1. Draft Biodiversity and Community Knowledge Protection Act, 1998

This draft reaffirms the sovereign right of the state over natural and biological resources and the authority of the national government to determine access to such resources. It also reaffirms Article 8 of CBD that seeks to promote wider application of innovation of the local and indigenous community with their approval and on equitable benefit sharing. The draft includes provisions to determine access to biological and genetic resources and related TK based upon PIC and fair and equitable sharing of benefits arising from the commercial use of such resources and knowledge. The draft recognises the global tendency towards affirmation of IPR over biological diversity, the related products and processes and declares it imperative for Bangladesh to protect its own resources against such backdrop. The draft declares the patenting of life forms as against the moral, intellectual and cultural values of the people of Bangladesh. Access, use and innovations that have biological and genetic resources at the center shall be guided by this principle. It also prohibits all forms of monopolisation of biological and genetic resources and related TK and culture.

1.2.1.1. Scope and coverage

The draft includes all biological and genetic resources, related TK and their derivatives within the jurisdiction of the country. It implies all varieties in life forms including plants, animals, fish, micro-organisms, cell lines, genetic material's characteristics, traits, products and processes involved therein. The traditional use and exchange of biological and genetic resources shall remain outside the purview of the proposed law. For the purposes of this draft, biological resources

include all biological resources, organisms or parts thereof, populations, or any other biotic components of ecosystems of Bangladesh. Genetic resources shall mean resources related to the genetic material and includes material of plant, animal, microbial or other origin containing functional units of heredity.

1.2.1.2. Provisions on access includes PIC and mutually agreed terms

The draft declares the indigenous, local, fishing and farming communities as the stewards and custodians of biological and genetic resources. No access to such resources shall be allowed without PIC of the communities. Inventions arising out of such resources shall not be sold or otherwise transferred without PIC of the communities. Access to and use of such resources for economic transactions and trade will be based on mutually agreed terms beneficial to both, the economic agents and the communities. The state shall not have the power to negotiate access without the full participation of other co-owners. Where access is allowed, the state shall ensure payment of royalties or compensation where applicable. The state shall ensure the right of the communities to deny collection of biological and genetic resources. The community of the country of origin must also be informed about entry of such resources to Bangladesh.

1.2.1.3. No IPR on accessed resources or products

The general conditions regulating access to biological and genetic resources declare certificate of intellectual property or similar certificate and licenses over such resources or products of such resources and process invalid and illegal. Any certificate of IPR or similar certificate of licenses upon resources/products/processes resulting from any such access shall be invalid and illegal. The draft, however, requires the National Biodiversity Authority (NBA) to study and recommend policies and regulations on the utilisation of biological and genetic resources, including IPRs and community rights in accordance with the draft. According to the draft,

- **Access shall be allowed:** to undertakings being carried out within Bangladesh; to undertaking outside Bangladesh when NBA can ascertain benefits in terms of enhancement of biodiversity; and with written PIC of

NBA and concerned community.

- **Access shall be denied:** to collector accused of irregular and unauthorised transaction; and to collector who has collected specimen in any country without PIC and without written commitment from the collector that research reports and results shall be provided to NBA and concerned community.

1.2.1.4. Procedure for access

The draft lays down a detailed procedure as to how request for access would be made and also the requirements and conditions for such access. The draft also requires the collector to inform NBA while applying for access about proposed mechanism and arrangements for benefit sharing. Such sharing of benefit shall include knowledge, technology and/or financial transfer, involvement of the country in research and development etc. The collector shall also give indication of the benefits, whether economic, technical, biotechnological, scientific, cultural, social or otherwise that might derive to the country and concerned communities.

1.2.1.5. Access is conditional to benefit sharing

After fulfilling the requirements stipulated in Section 13 of the draft and upon scrutiny of the application for access by NBA, an agreement may be signed by NBA and the collector allowing access. As a minimum requisite, such agreement shall be specific on the terms and conditions of equitable benefit sharing, including transfer of technology, sharing of research result, participation by Bangladesh in the economic, social and environmental benefits as may accrue from processes and products obtained through use of collected resources. Where the collector is not a national of Bangladesh, the state in the jurisdiction of which he/she operates must guarantee to ensure compliance with the mutually agreed terms of the agreement and enforce the same.

In case commercial benefit is derived, the collector shall pay, at least, a defined percentage of benefits, not less than 50 percent of net monetary gain from direct or indirect use of biological and genetic resource in respect of which access was

given. The agreement for access shall also contain a commitment that the collector would abide by the law and other relevant rules, including rules on biosafety. Access may be restricted or prohibited in case of non-compliance with rules on biosafety and food security.

It has been observed that the frequent reference to biosafety rules will make the related provisions of this draft infructuous as such rules have not been drafted nor are there any such initiatives. Moreover, it is not clear how the draft matches with the obligation of Bangladesh under TRIPS. It is noted that in deviation from TRIPS, the draft exempts all life forms from patentability. To ensure that such aspirations of the drafters of the proposed law get recognition, the same must receive appreciation at the policy level. A law of such vital importance must not be kept pending and must be finalised with wider consultations with the concerned stakeholders and people's participation in the law making process.

1.2.2. Draft Plant Varieties Act, 1998

This draft regulates the commercial transaction of plant varieties, including new plant varieties in Bangladesh. The provisions of this draft are to be interpreted in the context of the draft on biodiversity and its provisions on ABS. The draft has overriding power and any other law that to the extent of its inconsistency with this draft shall be void and discarded. For the purposes of this draft, 'plant' shall mean any living organism in the plant kingdom, fungus kingdom excluding bacteria and other micro-organism. The other definitions provided in the draft include the definitions of plant variety, community variety, local variety, transgenic plant, genetic material and propagation material.

1.2.2.1. Nature of protection

'Protection' to be accorded under this draft shall always mean defined and specific commercial privileges, whether explicitly mentioned or not, approved and granted to an innovator by NBA. Such protection shall not constitute any generalised IPR and may vary from applicant to application on the basis of nature of innovation. It is to be noted that the draft on biodiversity has not

defined the ‘protection’ term. In general, the draft on plant varieties does not recognise any claim of new variety for private IPR protection. It is only when communities recognise an independent human agency over and above the social process and the innovation serves definite and useful needs of the people of Bangladesh that protection may be accorded under the draft.

A new plant variety for protection under the law must be a hitherto non-existent variety, have consistent, stable and distinctive specific traits. For a new plant variety, NBA may either give ‘citation of award’ (where no protection for personal gain or commercial privilege is sought) or ‘commercial permit’ in the name of New Plant Variety Certificate.

To be eligible for consideration for commercial privileges, the new plant variety must meet definite and useful needs of the people of Bangladesh. It is only the recipient of the New Plant Variety Certificate, who can commercially produce, sell or distribute, offer, import into or export from Bangladesh such variety or the propagation material. The permission for export must be pre-conditional to the fact that there will be no claim of IPR over such exported material.

1.2.2.2. Breeders’ rights

A breeder may claim commercial privileges over hybrid only if the parents are available in Bangladesh as community variety in the public domain. The protection shall, in no way, affect the rights of farmers to have unencumbered access to biological and genetic resources of Bangladesh and related TK. Also the rights to collect, conserve, use etc., of plants for personal and non-commercial purposes shall not be affected under the privileges proposed under the draft. For improvement or development of local variety, common variety and wild variety for commercial purposes and also for commercial transaction of plant varieties or materials to propagate plants, a commercial permit shall be needed.

1.2.2.3. Treatment of foreign nationals

The draft is specific in naming those who can apply. Nationals of Bangladesh and other countries also may apply for protection provided the country to which he/

she belongs recognises the biodiversity law of Bangladesh; allows Bangladeshi national to apply for similar protection in that country; and has headquarters in a country that is a signatory to CBD.

The draft distinguishes between local/widespread/common plant variety and new plant variety. This draft shall protect the later variety for commercial privileges and award while the former are protected under the draft Biodiversity Protection Act. The great challenge that remains to be met is to ensure that the 'nature of protection' as proposed under the draft is 'effective' as envisaged in Article 27.3 (b) of TRIPS. The conditional approval to foreign nationals may well contradict Article 3 of TRIPS that requires Members to accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to IPR protection. Although the protection proposed under the draft is not IPR and hence, it does not call for application of Article 3, in ensuring its 'effectiveness', if the obligations under TRIPS have to be met, it may need modification both in the nature of protection and treatment of foreign nationals.

1.2.3. Draft Plant Variety Protection Act, 2002

In contrast with the draft Plant Varieties Act, 1998, that to a great extent seemed to have referred to CBD, this draft seeks to fulfill the obligation of Bangladesh under Article 27.3(b) of TRIPS.

1.2.3.1. Nature and term of protection

The draft seeks to protect two groups, the 'breeders' and 'farmers'.

For breeders: The protection to be accorded to the breeders under a New Plant Variety Certificate shall entitle them to exclusive commercial exploitation of the protected varieties of plants. However, for a New Plant Variety Certificate, the varieties must have the characteristics of novelty, distinctness, uniformity, stability and utility. A variety that uses genes involving terminator technology shall not be protected. Also transgenic plants/genetically modified organisms (GMOs) without Environment Impact Assessment (EIA) as to harmlessness shall

be rejected any protection. The draft, however, omits the definition of transgenic plants/GMOs. The protection to a breeder shall be 20 years for fruits, tree species and vines, and 15 years for all other species of annual habit. In dealing with eligibility for application, the draft adds one more condition in stating that the applicant shall be eligible if he/she is national of a country that is party to the Gene Treaty. Also the draft, compared to the older one, is more stringent in declaring applicants not eligible if he/she is from a country that has not ratified CBD. The 1998 version of the draft on PVP has only demanded the signing of CBD and not the ratification of it.

For farmers: The draft aims at protecting and promoting the rights of the farmers. Such rights include:

- right to protect their TK relevant to PGRs from being accessed in formal sector without compensation;
- right to claim significant contribution to a registered variety;
- right to claim an equitable share of benefits if their varieties have contributed to the registered variety; and
- rights to save, use, exchange and sell farm-saved seed/propagating material of registered variety for non-commercial purposes.

Violation of the provisions of this Act (draft) shall be liable to either imprisonment/fine or both. Such penal provision is an addition to the earlier draft.

1.2.3.2. Incentives to farmers and breeders

The preamble of the draft stipulates that the law aims at “providing incentives to breeders, individually or in groups or in collaboration with farmers, for better and stepped up breeding of new crop varieties”. The text in Section 23 (2) of the draft, however, suggests the opposite – the National Plant Variety Development Fund (NPVDF) to be established shall be utilised “to provide a range of incentives measures for farmers and local community to participate in various form of activities related to the development of new plant varieties in collaboration with private and public funded breeders...”. Since farmers and breeders have two distinct definitions, incentive to the one shall not necessarily mean and include

the other. The definition of farmers recognise the role of farmers in the development of varieties, but the definition of breeder has excluded the informal communities and has apparently referred to the formal sector by mentioning the breeder as ‘employer’. It is felt that the law should put more priority in providing incentives to the farmers while breeders may be given the necessary protection for commercial purposes.

1.2.3.3. Farmers’ representation

The draft proposes the formation of a statutory authority to be called the Plant Variety Protection Authority (PVPA) to grant either New Variety Certificate or Citations of Awards. PVPA shall be the implementing agency of the draft and not NBA as proposed under the earlier draft. It shall consist of 11 members with apparently no representation from the civil society or farmers’ community. It has to be noted that Section 38 of the draft on biodiversity protection has required representation of farmers in NBA.

2. Legal mechanisms in India

2.1. Country status

India signed CBD on 5 June 1992 and ratified it on 18 February 1994. Similarly, it signed and ratified ITPGRFA on 10 June 2002. As Bangladesh, India also became a WTO Member in 1995 since it was also a Member of the GATT, 1947. While India enacted Biological Diversity Act, 2002 under CBD, it introduced Protection of Plant Variety and Farmers’ Rights Act in 2001 under TRIPS.

2.2. Status of ABS and related laws

2.2.1. Biological Diversity Act, 2002

India introduced the Biological Diversity Act, 2002 keeping in consideration the principles of and its obligations under CBD. The Act provides for conservation of biological diversity, sustainable use of its components and equitable sharing of benefits arising out of the use of biological resources. This is an “Act to provide for

conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental.”

The Act provides a national administrative structure at all levels to monitor and regulate the access and sustainable use of biodiversity and promote its conservation. The administrative structure defined under the Act is as follows: a National Biodiversity Authority (NBA) at the centre; State Biodiversity Boards (SBBs) at the state level; and Biodiversity Management Committees (BMCs) at the *Panchayat* level.

The Act also provides rules for access to genetic resources for research and development on biodiversity to Indian citizen. No person within or outside India is eligible to apply for any IPRs for any invention based on any research or information on a biological resource obtained from India without prior approval from NBA. The Authority is entitled to impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilisation of such rights while granting approval.

Apart from local people, communities of the area, including growers and cultivators of biodiversity related material, and *Vaid*s and *Hakims*, no one can obtain genetic resources for commercial use without prior approval from SBB. One needs to get approval from NBA/SBB for using any biological resources of the country for whatever purpose so ever for research and commercial utilisation etc. Similarly, transfer of biological resources or knowledge will require permission from NBA. But the form of benefit sharing mechanisms to be chosen during granting of approval for access and transfer of natural resources by NBA may vary. Some of those could be granting of joint ownership of IPRs to NBA, transfer of technology, payment of monetary compensation and non-monetary benefits to the benefit claimers as NBA may deem fit.

The Act also provisions for creating National Biodiversity Fund and Local Biodiversity Fund. While the National Biodiversity Fund may be created out of the benefit accrued as a result of access fee submitted by a specific individual or group of individuals or organisations, Local Biodiversity Fund would be created

with grants from NBA, grants from SBBs etc. SBB is conceptualised as adviser to State Government, subject to matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of the benefits arising out of the utilisation of biological resources of states. Each local body (at the *Panchayat* level) shall constitute a BMC within its area for the purpose of promoting conservation, sustainable use and documentation of biological diversity, including preservation of habitats, conservation of land races, folk varieties and cultivars, domesticated stocks and breeds of animals and micro-organisms and chronicling of knowledge relating to biological diversity. NBA and the SBBs shall consult the BMCs while taking any decision relating to the use of biological resources and associated knowledge occurring within the territorial jurisdiction of BMC.

The Rules for Biodiversity Act 2002 have been announced in April 2004. However, it has been observed that through the Rules, the government has concentrated all control of the country's biodiversity in the hands of a few bureaucrats and experts thereby giving little attention to the rights of the local communities and farmers. BMCs at the *Panchayat* level have been given the responsibility to collect all the information related to biodiversity of their area to compile in People's Biodiversity Registers.

The Register shall contain comprehensive information on availability and knowledge of local biological resources, their medicinal or any other use or any other TK associated with them. But at the central and state level bodies, there is no scope for representation of farmers, tribals, pastorals or other communities. The Biodiversity Act mentions about the local community but the same is not defined under the law. Even the benefit sharing may be limited to mere contracts, material transfer agreements or cash payment that divide the community. In addition, no proper strategy or method has been defined to identify the community.

2.2.2. Protection of Plant Variety and Farmers' Rights Act, 2001

India enacted Protection of Plant Variety and Farmers' Rights Act, 2001 as per its commitment to comply with TRIPS. As its title suggests, the legislation is an attempt by the Indian Government to recognise the contribution of both commercial plant breeders and farmers in plant breeding activity. The Act aims to

establish “an effective system for the protection of plant varieties, the rights of farmers and plant breeders, to encourage the development of new varieties of plants”. Three key factors in introducing the legislation are:

- Protection of the rights of farmers for their contribution made at any time in conserving, improving and making available plant genetic resources for the development of new plant varieties;
- Protection of plant breeders’ rights to stimulate investment for research and development, both in the public and private sector, for the development of new plant varieties; and
- Giving effect to Article 27.3 (b) of the TRIPS Agreement on the protection of plant varieties (Dhar 2004).

The Act recognises the farmer not just as a cultivator but also as a conserver of the agricultural gene pool and a breeder who has bred several successful varieties. The Act makes provisions for such farmers’ varieties to be registered, so that they are protected against being scavenged by formal sector breeders. The rights of rural communities are acknowledged as well. According to the Act, the farmer “...shall be deemed to be entitled to save use, sow, resow, exchange, share or sell his farm produce including seed of a variety protected under this Act in the same manner as he was entitled before coming into force of this Act provided that the farmer shall not be entitled to sell branded seed of a variety protected under this Act. Besides these rights of farmers, the Act also ensures other rights to farmers:

- Benefit sharing based on compensation and operating through a mechanism where communities/farmers can make claims for such compensation; and
- Farmers' rights as ownership: the idea that farmers must be able to register their varieties in the similar fashion as breeders.

The Act provides for benefit sharing involving varieties registered under the Act in two circumstances. The first applies specifically to essentially derived varieties (EDVs) registered under the Act. In the second, any village or local community can claim benefit for contributing to the development of a variety registered under the Act. For a variety registered as an EDV, non-governmental organisations

(NGOs) or individuals can claim a share of benefits that may arise from the commercialisation of that variety on behalf of any village or local community. The Plant Varieties and Farmers' Rights Authority (PVFRA), the designated authority to implement the Act, to whom the claims for benefit sharing must be made, has been empowered to investigate the claims and to indicate the amount of benefit sharing should the Authority find the claim justified. The Authority will use two criteria to establish the justification of the claims. These are: the extent and nature of the use of genetic material of the claimant in the development of the variety for which the benefit sharing has been claimed; and the commercial utility and demand in the market of the variety for which the benefit sharing has been claimed (Dhar 2005)

The amount of benefit sharing, if any, would have to be deposited in the National Gene Fund by the breeder of the variety on which the claim has been made. In the second circumstance, any individual or NGO can make a claim on behalf of a village or local community for the contribution that the particular village or local community had made in the evolution of any variety registered under the Act. If, upon investigation, the claim was found justified by the PVFRA, after the breeder was given an opportunity to file objection and to be heard, an amount of compensation, as the Authority deems fit, would be deposited by the breeder in the National Gene Fund (Dhar 2005).

The National Gene Fund under this Act will be constituted out of the resources of: the benefit sharing from the breeder; the annual fee payable to the authority by way of royalties; by the compensation provided to the communities; and contribution from any national and international organisation and other sources.

The fund will be applied for disbursing shares to benefit claimers, either individuals or organisations, and for compensation to village communities. The fund will also be used for supporting conservation and sustainable use of genetic resources, including *in situ* and *ex situ* collection and for strengthening the capabilities of the *panchayat* in carrying out such conservation and sustainable use.

Under this Act, the provision of representation of farmers' organisation is governed by the centre and not the state or the local government. Therefore, the

selection could be politically biased. Similarly, the Authority is yet to provide definitions of distinctness, uniformity and stability as proposed in the PPVFR Act, which is a crucial factor in determining whether farmers would actually be able to register their varieties.

3. Legal mechanisms in Nepal

3.1. Country status

Nepal signed CBD on 12 June 1992 and ratified it on 23 November 1993. It, however, has not yet acted on ITPGRFA though discussions at different levels have been held regarding its relevance, prospects and challenges for Nepal. The country obtained WTO membership in April 2004 through accession.

As a Contracting Party to CBD, Nepal has prepared a draft Access to Genetic Resources and Benefit Sharing Act, 2002. Ministry of Forest and Soil Conservation, as a CBD focal point, has developed this draft. The Ministry is currently busy in finalising this draft for its enactment.

Similarly, Ministry of Agriculture and Cooperatives has prepared a draft Plant Variety Protection and Farmers' Rights Act, 2004 as part of Nepal's commitment at the WTO to enact a PVP law. Unlike on the draft on benefit sharing, there have been limited consultations on this draft in Nepal.

3.2. Status of ABS and related laws

3.2.1. Draft Access to Genetic Resources and Benefit Sharing Act, 2002

This draft deals with community rights relating to TK and benefit sharing. It has envisaged the creation of an autonomous National Genetic Resources Conservation Authority for the conservation, promotion and sustainable use of genetic resources and genetic materials that exist in the Kingdom of Nepal.

According to the draft, the Authority will also be responsible for sharing the benefits from access to, use and export of such resources and materials equitably

and judiciously, and protecting the rights and interests of the local community with regard to their TK, skill, innovation and practice. The draft makes it mandatory for anyone to conclude an access agreement with the Authority – whether for scientific research purpose or for commercial use.

The draft states that without acquiring a license, no one shall have the access to, use and export of genetic resources. But the draft exempts the local communities for the use of genetic resources through TK, skill, innovation, technology and practice. As per the draft, any person or organisation intending to access, use or export genetic resources and TK, shall be required to submit a proposal to the Authority, in the format as prescribed, along with the technical and benefit sharing reports, preliminary study report, and pay the fee, as prescribed.

On receipt of such a proposal, public hearing shall be organised following the process mentioned below:

- The Authority, after examining the proposal submitted by the proponent, shall forward the statements contained thereto and other statements as prescribed, to the concerned locally elected body, local community and organisation for public hearing. A notice thereto shall also be published in the national and local newspapers.
- The concerned Village Development Committee (VDC) or Municipality, upon the receipt of the notice as stated above, shall solicit the local residents for public hearing with a maximum of 15 day notice. A notice thereto shall be furnished to the concerned district level offices.
- The concerned VDC or Municipality on the basis of reactions made by the participants solicited pursuant to above issues shall make necessary recommendations to the Authority.
- Notwithstanding anything as contained above, the Authority may make necessary arrangements for public hearing through an appropriate locally elected body by prescribing appropriate procedures to solicit reactions of the local community on access to, use and export of genetic resources sought for in the proposal, if such resources occur in two or more VDCs.
- The presence of the proponent or his/her representative is mandatory in the public hearing.

The draft envisages engaging local bodies and communities in public hearings, thereby facilitating the process of PIC. This provision, to some extent, ensures the participation of communities in the benefit sharing process. However, whether public hearing can be taken as a complete process for PIC is still being debated. It is being argued that in public hearings, local communities will not be able to understand the issues at stake, neither they would be able to negotiate favourable terms of benefit sharing.

With regard to benefit sharing arrangement, the draft has underlined the sharing and distribution of benefits as follows:

- 50 percent to the local community, individual or organisation; 30 percent to the Authority's fund and the remaining 20 percent to the government revenue, if the ownership of the resource lies with the local community, individual or organisation.
- 50 percent to the government revenue; 20 percent to the local community and the remaining 30 percent to the Authority's fund, if the ownership of the resource lies with the Government of Nepal.
- For the purpose of benefit sharing pursuant to the above, the benefits shall be shared with the local community on the basis of its affiliation with the concerned VDC, Municipality or District Development Committee (DDC).

3.2.2. Draft Plant Variety Protection and Farmers' Rights Act, 2004

Following its commitment to implement TRIPS at the national level, Nepal has prepared the draft Plant Variety Protection and Farmers' Rights Act, 2004. The draft aims to ensure the rights of farmers and at the same time the rights of breeders. The draft spells the rights of farmers over their resources and TK, also provisioning for ABS and PIC. Regarding the sharing of benefits that arise out of the utilisation of genetic resources, the draft states that it will be on the basis of the Access and Benefit Sharing Act of Nepal, which is currently in the draft form (see above). Some of the remarkable features of the draft are:

- **Definition of farmers:** The draft has defined farmers as those people,

who are engaged personally in either their own or other's land for farming, or those who are engaged in farming in their own land by hiring labourers. People who are engaged individually or in a group to conserve wild and traditional plant varieties and those who are engaged in selecting and identifying special characteristics of plants to establish the unique features of plant species are also defined as farmers.

- **Collective and individual rights of farmers:** The draft has envisaged farmers' rights both as individual and collective rights. Whereas an individual farmer can exercise his/her individual rights by himself/herself, the collective rights of farmers will be exercised either through farmers' organization or local body, like the VDC or farmers' group.
- **Rights to save, exchange, reuse and sell farm-saved seed and propagating material:** The draft has explicitly spelled out these traditional rights of farmers. According to the draft, farmers can save their farm produce to use them in the future as seed. They can also reuse and exchange their material, as required. This has considerably lessened farmers' burden of buying seed for every harvest. The draft has even allowed farmers to sell their seed, but in non-branded form. Indeed, the draft has not only provisioned for farmers' rights but has also balanced it with the rights of breeders.
- **Compensation mechanism:** One of the most important features of the draft is the compensation mechanism. The draft has provisioned for the compensation mechanism in such a way that seed companies would have to compensate the farmers if farmers fail to get their harvests as claimed by the seed companies. Moreover, if seed companies do not provide adequate information or mislead farmers with false or wrong information, they ought to provide compensation, in cases of any loss to farmers.

4. Legal mechanisms in Pakistan

4.1. Country status

Pakistan signed CBD on 5 June 1992 and ratified it on 26 July 1994. The country acceded to ITPGRFA on 2 September 2003. Pakistan was also a GATT Member and hence became a WTO Member in 1995. Currently, there is no legal mechanism for ABS in Pakistan. The government has shown its willing-

ness to implement an ABS regime in international forums, which is evident from its submissions like report²³ to the World Summit on Sustainable Development (WSSD) in 2002. At the national level, the government has taken some steps towards the plant breeders' rights protection and has drafted a Plant Breeders' Rights Ordinance, on which discussions at different levels have been held between 2000 and 2004. Similarly, a draft law on Access and Community Rights, 2004 has been prepared, which is an obligation of Pakistan under CBD.

4.2. Status of ABS and related laws

4.2.1. Draft Law on Access to Biological Resources and Community Rights, 2004

The Ministry of Food, Agriculture and Livestock is working on this draft. It provides fundamental grounds for ABS mechanism in Pakistan. The draft aims at protecting the rights of local (and traditional) communities over biological resources and their related knowledge, innovations and practices. The draft has been developed under the obligations of CBD and the preamble also states the country's commitment to implement the relevant provisions of CBD, in particular Article 15 on access to generic resources and Article 8(j) on the preservation and maintenance of knowledge, innovations and practices of indigenous and local communities.

The objectives of the draft are to:

- provide support to local communities and protect their rights over biological resources and their knowledge, innovations and practices;
- ensure conservation and sustainable use of biological resources, knowledge

²³ Pakistan submitted its Country Assessment Report at WSSD in 2002. The CAR stipulates Pakistan's commitment to WSSD on its Agenda 21 (1992). Pakistan had also participated in the development of WSSD Implementation Plan, 2002, which calls for negotiation on an "international regime" on ABS, within the framework of CBD.

- and technologies;
- provide an appropriate system of access based upon mutually agreed terms and subject to PIC of the state and the concerned local communities;
 - promote appropriate mechanisms for a fair and equitable sharing of benefits arising from the use of biological resources, knowledge and technologies as well as ensuring the participation and agreement of concerned communities in making decisions as regards the distribution of benefits which may derive from such uses;
 - promote and encourage the building of national scientific and technological capacity relevant to the conservation and sustainable utilisation of biological resources; and
 - provide appropriate institutional mechanisms for the effective implementation and enforcement of community rights and conditions of access to biological resources.

The draft also highlights the role of the competent national authority, which is responsible to grant permission after the signing of an agreement with the collector. Regarding permission, the draft mentions that “No import or export of any biological resources shall be allowed to and from the country unless the competent national authority confirms that a prior informed consent has been obtained from the country of origin”.

Article 5(1) recognises the community rights and benefit sharing stipulating “The State shall recognize and protect the rights of the local communities to collective benefit from their knowledge, innovations and practices acquired through generations (past, present and future) and to receive compensation for the conservation of biological resources in accordance with the provisions of this legislation and subsequent regulations”. To facilitate the implementation of the ABS mechanism, the draft also mentions about the process of institutional arrangements and establishment of a National Information System.

4.2.2. Draft Plant Breeders’ Rights Act, 2000

Federal Seed Certification and Registration Department of Pakistan prepared this draft. The draft has been developed with justifications like – the efforts of

public sector in breeding of varieties of wheat, rice, cotton and other crops have been commendable but successful hybrid breeding system is still lacking in the country. There is a need to acknowledge the vital role of the private seed sector in seed production and marketing, and in order to stimulate plant breeding, crop varieties have to be protected through a plant variety protection system.

In the draft, the ownership of a variety or a successor is entitled to apply for a Certificate of Plant Breeder's Rights, provided the owner is a natural person, who is a national or resident of Pakistan or a legal person having its registered office in Pakistan.

The draft entitles farmers' rights as "Nothing contained in this Act shall affect a farmer's traditional right to save, use, exchange, share or sell his farm produce including seed of a protected variety under this Act except where a sale is for the purpose of reproduction under a commercial marketing arrangement". The draft allows plant breeders' rights for GMOs. It allows the multinational companies (MNCs) to freely exploit the TK of the communities.

It is surprising that a penalty clause, which would be vital for regulating the MNCs, has been dropped while revising the draft. The clause had allowed for penalty/compensation in the case of hazardous effects of a variety certified. Cancellation of the plant breeders' right certificate is the maximum punishment retained in the latest version of the draft. It, however, does not provide any punishment to authorities responsible for implementation in cases of contravention and violation.

The draft has not been promulgated, so far, due to strong opposition from the civil society and farmers' groups. They have criticised the draft saying that it only guarantees the rights of the breeders and not of the farmers. The very first problem lies in its nomenclature. It is the legislation for breeders' rights and not for farmers' rights.

It does not also address benefit sharing/royalty payments to communities. The draft neither recognises the collective rights of the farming communities nor

deals with the significance of PIC.

5. Legal mechanisms in Sri Lanka

5.1. Country status

Sri Lanka signed CBD on 10 June 1992 and ratified it on 23 March 1994. Sri Lanka was also a Member of the GATT and it became a WTO Member in 1995. In order to comply with the TRIPS provisions of the WTO, the country enacted a new Intellectual Property Act in 2003. Like Nepal, Sri Lanka too has not acted on ITPGRFA.

5.2. Status of ABS and related laws

In line with the provisions of TRIPS, Sri Lanka did not only introduce a new Intellectual Property Act in 2003 but also prepared a draft on the protection of new plant varieties. However, this draft is based on the 1991 version of the International Union for the Protection of New Varieties of Plants (UPOV) Convention²⁴, which severely restricts the rights of farmers to save, exchange, reuse and sell farm-saved seed, among others.

5.2.1. Biodiversity Conservation Action Plan, 1998

After ratifying CBD, as a first step for its implementation, Sri Lanka prepared the Biodiversity Conservation Action Plan (BCAP) in 1998. Apart from the conservation of biodiversity, the Action Plan has addressed the issue of protecting TK in relation to biodiversity. More importantly, BCAP has recognised the necessity of having laws and regulations to regulate access to country's genetic resources and to ensure equitable sharing of benefits from their use. Accordingly, it has provided the following recommendations to the government:

²⁴ UPOV is a convention tilted in favour of the commercial plant breeders and seed companies of the developed countries such as the European countries and the USA.

- Providing legal recognition to the sovereign right of the state over its biological resources;
- Establishing a legal framework for the control and regulation of access to genetic resources;
- Providing a legal framework for the recognition and protection of indigenous knowledge;
- Drafting a legally binding regulation to ensure that research on any component of biodiversity in Sri Lanka by non nationals would be carried out on the basis of an agreement with a local institution and in close collaboration with Sri Lankan scientists. Moreover, the outcome of such research, including the information that is collected during the course of the research, is made available to Sri Lankan scientists and institutions.

At present, this Action Plan is being updated by the Biodiversity Unit of the Ministry of Environment and Natural Resources and an addendum to it has been prepared. As part of the review of the BCAP, a study has been conducted to look into the gaps of regulating access to biological resources. This study concludes that while Sri Lanka does not lack laws to conserve its biological resources, it lacks laws to regulate access to such resources. The study has also identified ITPGRFA as an important international legal instrument to create a national ABS law, making a recommendation that the country should act on it.

5.2.2. Draft Access and Benefit Sharing Law, 2000

Sri Lanka prepared a draft law on Access and Benefit Sharing in 2000. The draft aims at regulating and facilitating access to genetic resources ensuring their conservation and establishing a benefit sharing mechanism. It was claimed²⁵ that the draft was based on certain fundamental principles of the Constitution of Sri Lanka, 1978, CBD and other relevant national/international instruments. However, this draft was not enacted due to strong opposition from the civil society. The civil society objected to this draft on two counts.

²⁵ According to the “Recommendations for the Regulation of Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Report” submitted to the Biodiversity Secretariat of the Ministry of Forestry and Environment.

Firstly, the draft dealt only with genetic resources as opposed to biological resources, which covers a broader spectrum. Their concern was that giving access to genetic material by separating it from its biological resource would not only be difficult, but almost impossible. This could result in the recipient automatically gaining access to a large amount of biological resource, not covered by the ABS regime, consequently obtaining the genetic resource/material without PIC of the holders of such resources.

Secondly, the draft had provisioned for the establishment of an Inter Agency Committee to decide on the mechanisms of PIC for the purpose of granting access to genetic resources. As per the draft, this Committee was to be comprised of government officials and two members representing the NGO community, appointed by the Minister. This could give a leeway to the officials to give PIC on behalf of the holders of indigenous knowledge and genetic resources, without their consent.

5.2.3. Draft National Institute of Biodiversity Act, 2003

The Ministry of Environment and Natural Resources of Sri Lanka drafted the National Institute of Biodiversity Act, 2003 for the establishment of a National Institute of Biodiversity in Sri Lanka. It was a part of the Sri Lankan Government's *Regaining Sri Lanka* strategy that would provide for the scientific infrastructure necessary to support future efforts to protect and promote biodiversity. However, due to strong oppositions from the civil society and the environmentalists, who perceived this draft as detrimental to the biological resources of Sri Lanka based on the powers to be given to the institute, it could not be enacted.

Chapter

3

Conclusion

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Launched in December 1994 at Nepal by a consortium of South Asian NGOs, SAWTEE is a regional network that operates through its secretariat in Kathmandu and 11 member institutions from five South Asian countries, namely Bangladesh, India, Nepal, Pakistan and Sri Lanka.

The organisation's mission is to enable South Asian communities to benefit from and minimise the harms of changing regional and global economic paradigms. The overall objective of SAWTEE is to build the capacity of concerned stakeholders in South Asia by equipping them with knowledge, information and skills to voice their concerns, particularly in the context of liberalisation and globalisation.

SAWTEE, in collaboration with its partner organisations in five South Asian countries, has been implementing the Regional Programme on Securing Farmers' Rights to Livelihood in the Hindu-Kush Himalayan Region since 2001.

