

Review of Article 27.3 (b) of

TRIPS Agreement**POLICY ISSUES FOR SOUTH ASIA****INTRODUCTION**

There is a growing realisation among biodiversity-rich developing countries that the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organisation (WTO) is in conflict with the spirit and objectives of the Convention on Biological Diversity (CBD)¹. Most of them view that TRIPS, which subordinates public goods to private property rights, undermines the equity principles of access and benefit sharing (ABS) and prior informed consent (PIC) of CBD (*see Box 1*).

They consider that TRIPS has created a route for the inventors to obtain “excessively broad patents” in a manner that perpetuates and legitimises biopiracy (*see Box 2*) and threatens the rights of indigenous, local and farming communities over their biological resources and associated traditional knowledge (TK). On the issue of patenting of life forms allowed under TRIPS Article 27.3 (b), they argue that it has given rise to a number of ethical, religious, environmental and developmental concerns, putting further pressures, among others, on the livelihood of indigenous, local and farming communities of developing countries.

Currently, negotiations for the review of this Article are being held at the Council for TRIPS but there seems to be no consensus on how to move forward. While developed countries have corporate-driven agenda aimed



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at providing stronger intellectual property rights (IPRs) to their breeders and multinational seed and pharmaceutical companies, developing countries want TRIPS to be mutually supportive of CBD and recognise the rights of indigenous, local and farming communities.

In the backdrop of these issues, this Policy Brief presents the current state of play of review negotiations and analyses the positions of developed and developing countries on patents on life forms. The major objective of the Brief is to highlight policy issues that biodiversity-rich South Asian countries need to consider during the review process and implementation of ABS laws.

REVIEW OF TRIPS ARTICLE 27.3 (B)

TRIPS is considered to be the most contentious agreement of the WTO, mainly because of its provisions under Article 27.3 (b). With the intention of allowing patents on life forms, the Article, while dealing with exceptions to patentability, stipulates:

Members may also exclude from patentability...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...

The review of this Article, after four years of coming into force of TRIPS, was mandated by the Article itself. The review, however, did not begin in 1999 due to continued tussle between developed and developing countries. Finally, the review began in 2000 but it was in December 2001 that Paragraph 19 of the Doha Dec-

Box 1: Access, benefit sharing and prior informed consent

Access is the acquisition of biological and genetic resources or associated TK, innovations, technologies or practices.

Benefit sharing is the sharing of benefits (either in a monetary or a non-monetary form or both) arising out of the commercial use of resources or TK between the provider (owner) and receiver (user) of resources and TK.

Prior informed consent is the consent that the receiver (user) of resources and TK, based on complete and accurate information, needs to obtain from the provider (owner) of resources and TK.

laration – agreed during the Doha Ministerial of the WTO – provided a more appropriate basis for the review. In Doha, WTO Members made the following decision:

We instruct the Council for TRIPS...to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.

However, despite a series of negotiations under this mandate, it is unlikely that Members will come to a consensus in the foreseeable future on these issues. The positions taken by developing and developed countries in their proposals submitted to the Council for TRIPS

explicitly show that there still exists considerable divergence of views.

Developing Country Positions

There are two “major positions” of developing countries in the TRIPS review process. The African group has mainly taken a position against patents on life forms, raising several ethical and cultural concerns. The group has proposed that Article 27.3 (b) should be revised to prohibit patents on plants, microorganisms and essentially biological processes for the production of plants and animals, including non-biological and microbiological processes.² Another group of developing countries that includes Bolivia, Brazil, Cuba, Ecuador, India, Peru and Thailand does not, as such, reject patents on life forms but demands patent applicants to fulfill the conditions of ABS, PIC and disclosure requirement.

Some developing countries also opine that the Article

Box 2: Preventing “biopiracy”: A key developmental concern of developing countries

Biopiracy does not merely mean unauthorised extraction and use of biological and genetic resources but also includes authorised extraction and use of such resources on the basis of an exploitative transaction. Such exploitative transaction occurs, when, among others, donors of the resources (who are the most ill-informed) are not adequately compensated. Developing countries consider that TRIPS does not make any attempt to curb biopiracy. Most of these

countries, therefore, want TRIPS to recognise the ABS and PIC principles of CBD and incorporate disclosure requirement as a condition to obtain patents. Examples of some of the properties of select biological resources that are in use in developing countries but patented by individuals and corporations of developed countries, with the claims that they fulfilled all the criteria of obtaining the patent, have been shown below.

Local/ English name	Botanical name	Endemic to	Prior art/use	Main patent provided to/for	Patent no.
Quinoa	Chenopodium quinoa	Andes region	Staple food crop	The professors from Colorado State University for Apelawa, a traditional variety of Quinoa	US 5,304,718
Ayahuasca	Banisteriopsis caapi	Amazon basin	Medicinal plant	International Plant Medicine Corporation (IPMC) for developing psychiatric drugs	US PP 5,751
Basmati rice		South Asia	Premium food	RiceTec, for long grain, aromatic variety of rice	US 5,663,484
Bitter gourd	Momordica charantia	Asia	Anti-infection, anti-tumor	National Institutes of Health and New York University for the use of the bitter melon’s protein for treating tumors and HIV	US 5,484,889, US 5,900,240, EP 552,257, JP 6,501,689
Neem	Azadirachta indica	Asia	Pesticide contraceptive, tooth paste, etc.	W R Grace, Native Plant Institute, Japanese Terumo Corporation, for pesticide and toothpaste, etc.	US 5,411,736, US 5,409,708, EP 436,257
Turmeric	Curcuma longa	South Asia	Wound healing	University of Mississippi Medical Centre for wound healing property	US 5,401,504

Note: Some of the above mentioned patents have been revoked after legal challenges.

Adapted from: Dutfield, Graham. 2004. “What is Biopiracy?”. Paper presented at the International Expert Workshop on Access to Genetic Resources and Benefit Sharing. Organised by Comision Nacional para el Uso y Conocimiento de la Biodiversidad (conabio). 24-27 October. Cuernavaca. The table is drawn from: Adhikari, Ratnakar. 2005. “Protecting Farmers Rights through Access and Benefit Sharing Regime: Nepalese Perspective” in *Troubled Times: Sustainable Development and Governance in the Age of Extremes*. Islamabad: Sustainable Development Policy Institute (SDPI) and SAMA Publisher.

should be amended to prohibit the patenting of inventions based on TK or those that violate the provisions of CBD.³ Similarly, a group of developing countries has asked for clarifying the artificial distinction between biological and microbiological organisms and processes. The group has also called for clarifying that provisions on patenting of microorganisms only apply to genetically modified microorganisms. There is also a submission from some developing countries suggesting that the obligation of developing countries to implement Article 27.3 (b) should take effect five years after the completion of the review of the provision.⁴

A group of developing countries led by Brazil and India has specifically called for “mandatory disclosure of the source of origin of the genetic resources and associated TK” (IP/C/W/429/Rev. 1). And, on 18 March 2005, Brazil and India, together with six other developing countries – Bolivia, Colombia, Cuba, Dominican Republic, Ecuador, Peru and Thailand – submitted another proposal (IP/C/W/442).

This proposal goes much beyond the disclosure requirement and evidence of PIC (circulated in the Council for TRIPS as IP/C/W/429/Rev.1 and IP/C/W/438 respectively). It proposes that the patent application based on genetic resources or TK should include an evidence of benefit sharing with the country of origin and if it is not fulfilled, the processing of such application should be stopped or the application itself should be withdrawn. In addition, the proposal demands that if the failure to provide such evidence is discovered after the granting of patent, it should be revoked or the rights could be transferred wholly or in part and criminal and/or civil sanction can be applied.⁵

Developed Country Positions

A group of developed countries (the United States of America-USA, Australia and Japan), which has also gathered the support of Korea and Singapore, is of the view that in the interest of scientific advancement, transparency and technology transfer, it is necessary to provide patents on plants and animals and an international rule is best suited for the purpose.⁶ This group has even argued that the exceptions to patentability mentioned in Article 27.3 (b) are unnecessary.⁷ Emphasising that there is no conflict between TRIPS and CBD,⁸ they state that there should not be further lowering down of standards of patent protection. In particular, while the USA and Singapore opine that TRIPS should not be used to enforce ABS rules, the USA and Japan view that ABS should be achieved by contracts, not under TRIPS.⁹

Unlike this group, the European Union (EU) has started showing some flexibilities, which is evident from its



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consent to include disclosure requirement within TRIPS. The EU, nevertheless, considers that the “failure to disclose, or the submission of false information should not stand in the way of the grant of the patent and should have no effect on the validity of the patent, once it is granted.”¹⁰ Similarly, Switzerland and Norway too have

offered some conditional support to incorporate disclosure requirement within TRIPS.

Current State of Play

Discussions on patents on life forms, ABS, PIC and disclosure requirement are not only taking place at the Council for TRIPS but are also being undertaken at the CBD forum. If Contracting Parties to CBD agree to establish an international ABS regime under CBD incorporating the concerns of developing countries, this will certainly help in addressing the unresolved issues in addition to adding credibility to the argument of developing countries to include disclosure requirement within TRIPS.¹¹

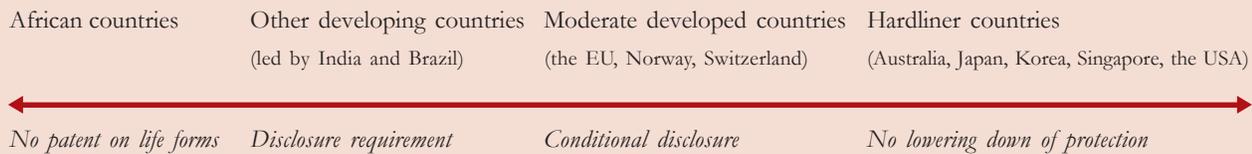
Besides, discussions on these issues are also taking place in other fora such as World Intellectual Property Organisation (WIPO) and International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Likewise, United Nations Conference on Trade and Development (UNCTAD) too is now mandated to undertake analysis on these issues. Hence, some expectations can be made that the negotiations being undertaken under these platforms would provide further momentum to resolve the intense international debate on the relationship between TRIPS and CBD.¹² Provided a well coordinated strategy is devised by developing countries to actively participate in these fora and influence the negotiations, there is a possibility that they would be able to get their development concerns addressed.

Realising such need, Commerce Minister of India, Mr Kamal Nath, prior to the WTO Ministerial held in December 2005 in Hong Kong, had issued a letter to 31 commerce ministers urging them to adopt an aggressive strategy and form a common position on the review of Article 27.3 (b). The idea was to influence the Ministerial to adopt a declaration similar to the Declaration on TRIPS and Public Health, adopted in the Doha Ministerial of the WTO in 2001. The Hong Kong Ministerial, however, did not make any decision to resolve the TRIPS/CBD debate. As a result, developing countries are still seeking ways to ensure that their interests are protected by TRIPS.

SOME ANALYTICAL ISSUES

If we observe the “major positions” of countries on the review of Article 27.3 (b), we find that their positions

Diagram: A continuum of “major positions” of WTO Members in the Council for TRIPS



run like a continuum (see the Diagram). This clearly means that in order to break the logjam, there is a need for them to be flexible and compromise in a way that balances the interests of all groups of countries. While the extreme proposals of the African group and the group led by the USA may be acceptable as the first order negotiating positions, neither of them, in the present forms, is likely to help build consensus.

The position of the USA-led group is understandable given the pressure from the corporate lobby. The requirement to pay royalties to the donors of the genetic resources and associated TK is certainly not a provision they want in TRIPS. They have already highlighted some practical problems such as difficulty in tracing the original donors and complications in ABS arrangements as all the genetic materials so acquired cannot be commercialised. They have instead proposed a “contract based” arrangement for benefit sharing, that too, not under the TRIPS Agreement.

The proposal of the African group too may not be acceptable to and in the interest of all countries. They

consider that the restriction on patents on life forms can be an approach to address the ethical, religious, environmental and developmental concerns, curb biopiracy and conserve the biological resources but it can, as developed countries argue, also discourage bioprospecting and necessary research and investments in the agricultural and health sectors. This argument seems logical to some extent as developing countries should not undermine their potential to benefit from bioprospecting. There may exist considerable scope to realise such potential provided they make concerted efforts, for example, through South-South Cooperation on research and development (R&D).

Similarly, as noted above, there is a proposal from some developing countries demanding that TRIPS should include disclosure requirement. Developing countries should, however, realise that though disclosure requirement can make sense as a pragmatic choice, it may not be a negotiating tactic. Some commentators have argued that the groups of countries that support disclosure requirement offered a compromise deal too early

Box 3: Disclosure requirement: A proactive agenda of developing countries

Since biopiracy can restrict the rights of indigenous, local and farming communities, a means to prevent the same and reward them is necessary. Precisely with this idea in mind, the Contracting Parties to CBD have included “sustainable use” and “fair and equitable benefits” as the major objectives of the Convention. Developing countries should pay increased attention in setting a proactive agenda to discourage biopiracy and uncompensated commercial use of genetic resources and associated TK. In this regard, disclosure requirement could be considered a better option for the following reasons: *First*, it helps in achieving the objectives of CBD by facilitating the ABS and PIC processes and discouraging biopiracy. *Second*, this requirement serves as a mechanism to track down the patent applications that are based on genetic resources and related TK, and make adequate challenges in cases of specious patents. *Third*, while ensuring adequate compensation to the donors of the genetic resources or

TK, this requirement will ensure continued flow of investment in R&D on genetic resources and TK, required for their value creation. *Fourth*, it will provide incentives to the communities to conserve and make sustainable use of genetic resources and associated TK by putting in place a required incentive structure. *Fifth*, this requirement not only obliges patent applicants to comply with the ABS legislation of the host country but also enables patent offices to be more vigilant while examining patent applications. *Sixth*, this system enhances the credibility of the patent system as well as contributes to achieving the principle objective of creating a balance of rights and obligations between the patent holders and donors of the genetic resources and TK. *Seventh*, placing the onus on a patent applicant to disclose the basis of the claims is a step that can preempt any misuse of patent laws and thereby prevent biopiracy of resources or misappropriation of TK.

Adapted from: Adhikari, Ratnakar. 2005. “Emerging Issues Relating to Conflict between TRIPS and Biodiversity: Implications for South Asia” in *South Asian Yearbook on Trade and Development*. New Delhi: Centre for Trade and Development (CENTAD); and Dhar, Bishwajit and R. V. Anuradha. 2005. *Reconciling TRIPS and CBD through Disclosure Requirement*. Policy Brief. No. 11. Kathmandu: South Asia Watch on Trade, Economics & Environment (SAWTEE).

in the negotiation stage.¹³ Kanniah (2005) terms it “an offer that has not dislodged the dogged stand of the developed countries”. Therefore, besides developing positions on issues of their interest, such as disclosure requirement, it is equally important for them to devise a tactful negotiation strategy for review negotiations. A number of developing countries are already in favour of disclosure requirement. As an indication of growing support, the African group too has recently supported this proposal.¹⁴ Moreover, some developed countries, mainly the EU, have also become sympathetic to this proposal. Thus, there is a possibility that countries like the EU, Switzerland and Norway would act as bridge builders to convince the USA-led group to agree to include disclosure requirement in TRIPS.



Until countries – both developed and developing – find a common point of agreement on patents on life forms, ABS, PIC and disclosure requirement, there is no possibility of achieving a major breakthrough. There is, thus, a need of an agreement that protects the interests of all Members and creates a balance between IPRs and community rights. An attempt has been made hereunder to suggest a common point of agreement on the review of Article 27.3 (b).

Patenting on life forms can be allowed but with three conditions. *First*, only in cases of genetically modified plants, animals, organisms and associated non-biological processes, provided patent applicants prove that they are “inventions” and not mere “discoveries” (but such patents should be extended only to the extent of the use of specific genetic resource and should not cover all the genetic resources inherited in plants, animals or microorganisms). *Second*, provided Article 27.2 explicitly mentions that Members may also reject patents on life forms on grounds of ethical, religious, environmental and developmental concerns. *Third*, provided disclosure of source and country of origin of the used genetic resources or TK is made along with an evidence proving that ABS and PIC conditions have been fulfilled as per the spirit and objectives of CBD and the requirements of national ABS laws.

ISSUES FOR SOUTH ASIA

South Asian countries not only have common interests on issues concerning IPRs, biodiversity conservation and community rights, they also, to a significant extent, share a common natural and cultural heritage. However, till date, they have not been able to use the platform of South Asian Association for Regional Cooperation (SAARC) to devise strategies to address the

growing challenges of IPRs on biodiversity and people's livelihood. Moreover, despite their potential to benefit from biodiversity, TK and IPRs, they have not yet developed any policy mechanism to enhance South-South Cooperation on R&D, which is critical to help them realise the potential of biopros-

pecting in the region.

Outside South Asia, few developing countries have, so far, implemented ABS regimes, and most countries that did, have benefited little therefrom, essentially due to poor implementation and complex procedure.¹⁵ The experience of such countries shows that considerable efforts, resources and expertise are required to implement the ABS regime in practice.

In South Asia, India is the only country to have enacted ABS legislation. Other countries – Bangladesh, Nepal, Pakistan and Sri Lanka – had ratified CBD by 1994 but none of them have yet implemented ABS laws. They have prepared the draft laws but there still exists considerable scope for the improvement in the provisions, for which they need to conduct wider consultation with key stakeholders. While doing this, taking lessons from other countries, South Asian countries should understand that the enactment of ABS laws is a necessary but not sufficient condition for realising the objectives of CBD.

The process of the enactment and implementation of ABS laws entails capacity building of law enforcement and implementing agencies, patent offices as well as communities and their organisations. The enhancement of negotiation capacity of concerned agencies, particularly responsible for providing access to genetic resources and determining the benefit sharing mechanism, is equally important. These efforts require a significant amount of technical and financial resources, which countries in South Asia may not be able to afford. Finding a strategy to obtain technical and financial assistance for policy and law making and their implementation should, therefore, be a priority of these countries.

CONCLUSION AND RECOMMENDATIONS

The mandate given by TRIPS to review Article 27.3 (b), together with the consensus reached at Doha to examine the interrelationship between TRIPS and CBD, among others, provides a window of opportunity to developing countries, including countries in South Asia, to undo the possible damage that patent rules under TRIPS can cause. However, the progress made so far in the review process indicates that developed and developing countries need to show more flexibilities to

come to consensus on patents on life forms, ABS, PIC and disclosure requirement.

Given these issues, in the process of further negotiations for the review of Article 27.3 (b) and implementation of ABS laws, South Asian countries should:

- Bring the issues of patents on life forms, ABS, PIC and disclosure requirement at the forefront of SAARC agenda and develop a regional position for negotiations at the Council for TRIPS and other international fora.
- Collaborate with other countries such as the African and other mega-diverse countries, mainly in Latin America and East Asia, to develop a common position on patents on life forms, ABS, PIC and disclosure requirement and negotiate accordingly at the Council for TRIPS and other international fora.
- Make efforts to develop a feasible common ABS regime at the regional level, for which they can take references of and lessons from the Andean Pact and Association of South East Asian Nations (ASEAN) Model of Regional ABS Regime.
- Enhance South-South Cooperation on R&D to realise the potential of bioprospecting in the region.
- Develop a coordinated strategy to obtain required technical and financial assistance, including for the implementation of ABS laws in their territories. ■

NOTES

- ¹ CBD was signed at Rio de Janeiro on 5 June 1992. The Convention aims at ensuring conservation of biodiversity, sustainable use of biodiversity and its components and fair and equitable benefit sharing from the commercial use of genetic resources.
- ² See joint communication from the African Group. IP/C/W/404 dated 26 June 2003.

³ See notes by the WTO Secretariat. Draft Revision of Document IP/C/W/369.

⁴ Kenya on behalf of the African Group. IP/C/W/163.

⁵ See submission from Bolivia, Brazil, Colombia, Cuba, Dominican Republic, Ecuador, India, Peru And Thailand. IP/C/W/442.

⁶ The principal supporters of this view include countries like Australia, Japan, Singapore and the US. See Notes by the WTO Secretariat. Draft Revision of Document IP/C/W/369.

⁷ See submission from the US. IP/C/M/29.

⁸ See ICTSD. 2007. "Brief TRIPS Council Give Way to Informals" in *Bridges Weekly Trade News Digest*. Vol. 11, No. 6. Geneva: International Centre for Trade and Sustainable Development.

⁹ Adhikari, Ratnakar. 2005. "Emerging Issues Relating to Conflict between TRIPS and Biodiversity: Implications for South Asia" in *South Asian Yearbook on Trade and Development*. New Delhi: Centre for Trade and Development (CENTAD).

¹⁰ See communication from the European Communities and their Member States. IP/C/W/383.

¹¹ See ICTSD. 2007. Above note 8.

¹² See UNCTAD. 2004. *Sao Paulo Consensus*. Eleventh Session of UNCTAD. TD/L.380. 16 June. Sao Paulo. Para 101.

¹³ See Kanniah, Rajeshwari. 2005. "Review of TRIPS – Divergence in Developing Country Positions" in *Trade Insight*. Vol.1, No.4. Kathmandu: South Asia Watch on Trade, Economics & Environment (SAWTEE).

¹⁴ See ICTSD. 2007. Above note 8.

¹⁵ See Correa, Carlos. 2003. "The access regime and the implementation of the FAO International Treaty on Plant Genetic Resource for Food and Agriculture in the Andean Group countries" in *The Journal of World Intellectual Property*. Vol. 6, No. 6. November.

Launched in December 1994 at Nagarkot, Nepal by a consortium of South Asian NGOs, South Asia Watch on Trade, Economics & Environment (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. Registered in Kathmandu in 1999, the overall objective of SAWTEE is to build the capacity of concerned stakeholders in South Asia in the context of liberalisation and globalisation.



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