

Trade Related Aspects of Intellectual Property Rights (TRIPS)

- **The WTO Agreement on TRIPS**

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), negotiated during the Uruguay Round, introduced intellectual property rules for the first time into the multilateral trading system. The Agreement, while recognizing that intellectual property rights (IPRs) are private rights, establishes minimum standards of protection that each government has to give to the intellectual property right in each of the WTO Member countries. The Member countries are, however, free to provide higher standards of intellectual property rights protection.

The Agreement is based on and supplements, with additional obligations, the Paris, Berne, Rome and Washington conventions in their respective fields. Thus, the Agreement does not constitute a fully independent convention, but rather an integrative instrument which provides "Convention-plus" protection for IPRs.

The TRIPS Agreement is, by its coverage, the most comprehensive international instrument on IPRs, dealing with all types of IPRs, with the sole exception of breeders' rights. IPRs covered under the TRIPS agreement are:

The TRIPS agreement is based on the basic principles of the other WTO Agreements, like non-discrimination clauses - National Treatment and Most Favoured Nation Treatment, and are intended to promote "technological innovation" and "transfer and dissemination" of technology. It also recognizes the special needs of the least-developed country Members in respect of providing maximum flexibility in the domestic implementation of laws and regulations.

Part V of the TRIPS Agreement provides an institutionalized, multilateral means for the prevention of disputes relating to IPRs and settlement thereof. It is aimed at preventing unilateral actions.

Copyrights and related rights;

Trademarks;

Geographical Indications;

Industrial Designs;

Patents;

Layout designs of integrated circuits; and

Protection of undisclosed information (trade secrets).

(a) Copyrights and related rights

Part II Section 1 (Article 9 to Article 14) of the TRIPS agreement deals with the minimum standard in respect of copyrights.

Copyright is a right given by the law to creators of literary, dramatic, musical and artistic works and producers of cinematograph films and sound recordings. It is a bundle of rights including, inter alia, rights of reproduction, communication to the public, adaptation and translation of the work. There could be slight variations in the composition of the rights depending on the work.

The Copyright Act, 1957 protects original literary, dramatic, musical and artistic works and cinematograph films and sound recordings from unauthorized use. Unlike the case with patents, copyright protects the expressions and not the ideas. There is no copyright in an idea. The general rule is that a copyright lasts for 60 years. In the case of original literary, dramatic, musical and artistic works the 60-year period is counted from the year following the death of the author. In the case of cinematograph films, sound recordings, photographs, posthumous publications, anonymous and pseudonymous publications,

works of government and works of international organizations, the 60-year period is counted from the date of publication.

The Copyright Act, 1957 came into effect from January 1958. This Act has been amended five times since then, i.e., in 1983, 1984, 1992, 1994 and 1999, with the amendment of 1994 being the most substantial. The Copyright Act, 1957 continues with the common law traditions. Developments elsewhere have brought about a certain degree of convergence in copyright regimes in the developed world.

The Copyright Act is compliant with most international conventions and treaties in the field of copyrights. India is a member of the Berne Convention for the Protection of Literary and Artistic Works of 1886 (as modified at Paris in 1971), and the Universal Copyright Convention of 1951. Though India is not a member of the Rome Convention of 1961, the Copyright Act, 1957 is fully compliant with the Rome Convention provisions.

Two new treaties, collectively termed as Internet Treaties, were negotiated in 1996 under the auspices of the World Intellectual Property Organization (WIPO). These treaties are called the 'WIPO Copyrights Treaty (WCT)' and the 'WIPO Performances and Phonograms Treaty (WPPT)'. These treaties were negotiated essentially to provide for the protection of the rights of copyright holders, performers and producers of phonograms in the Internet and digital era. India is not a member of these treaties as yet.

Copyrights in the TRIPS Agreement

Protection of works covered by Berne Convention. (Art.9)

Protection of computer programs as literary works and of compilations of data. (Art. 10)

Recognition of rental rights, at least for phonograms, computer programs, and for cinematographic works. (Art. 11)

Recognition of a 50 years' minimum term for works owned by juridical persons, and for performers and phonogram producers. (Art 12)

Exceptions to exclusive rights must be limited to special cases, which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the rights-holder. (Art 13)

Recognition of rights of performers, producers, of phonograms and broadcasting organizations. (Art. 14)

(b) Trademarks

Part II Section 2 (Article 15 to Article 21) of the TRIPS agreement contains the provisions for minimum standards in respect of Trademarks.

A trademark is a distinctive sign which identifies certain goods or services as those produced or provided by a specific person or enterprise. Its origin dates back to ancient times, when craftsmen reproduced their signatures, or "marks" on their artistic or utilitarian products. Over the years these marks evolved into today's system of trademark registration and protection. The system helps consumers identify and purchase a product or service because its nature and quality, indicated by its unique trademark, meets their needs.

A trademark provides protection to the owner of the mark by ensuring the exclusive right to use it to identify goods or services, or to authorize another to use it in return for a payment. The period of protection varies, but a trademark can be renewed indefinitely beyond the time limit on payment of additional fees. Trademark protection is enforced by the courts, which in most systems have the authority to block trademark infringement.

There are two international treaties governing Trademarks -the Madrid Agreement Concerning the International Registration of Marks and the Madrid Protocol.

In India, the Trade Marks Act, 1999 was passed on 30th December 1999 and came into force on 15th September 2003. Before commencement of this Act, the Trade & Merchandise Marks Act governed the protection of trademarks in India, which has now been replaced by the Trade Marks Act. The Trade Marks Act, 1999 is in coherence with the provisions of the TRIPS Agreement. The new Act provides for registration of trademarks for services in addition to goods, and has increased the period of registration and renewal from 7yrs to 10yrs.

Trademark in the TRIPS Agreement:

Protectable subject matter includes any sign, combination of signs capable of distinguishing the goods or services from others. Registration depends on distinctiveness and use. (Art 15)

Rights on the owners of registered trademark conferred to prevent third party not having his consent, from using in course of trade relating to identical goods/ services. (Art. 16)

Exception to exclusive rights must be limited and take into account the legitimate interest of the trademark owner and of third parties. (Art. 17)

The minimum term of protection is seven years, indefinitely renewable. (Art. 18)

Requirements for use are to be limited in terms of both the minimum period of non-use and the admissibility of reasons for non-use. (Art. 19)

Special requirements for use are limited, as well as the conditions of licensing and assignment of trademarks. (Art 20)

A trademark may be assigned without transfer of the business to which it belongs. (Art. 21)

(c) Geographical Indications (GI)

Section 3 Part II (Article 22 to Article 24) of the TRIPS Agreement contains the provisions for minimum standards in respect of geographical indications.

Geographical Indications of Goods are defined as that aspect of intellectual property which refers to the geographical indication referring to a country or to a place situated therein as being the country or place of origin of that product. Typically, such a name conveys an assurance of quality and distinctiveness which is essentially attributable to the fact of its origin in that defined geographical locality, region or country. Under Articles 1 (2) and 10 of the Paris Convention for the Protection of Industrial Property, geographical indications are covered as an element of IPRs.

In India, the Geographical Indications of Goods (Registration and Protection) Act, 1999 came into force with effect from 15th September 2003. This Act seeks to provide for the registration and protection of Geographical Indications relating to goods in India. The Controller General of Patents, Designs and Trade Marks is also the registrar for the Geographical Indications, and the Geographical Indications Registry is located at Chennai.

GI in the TRIPS Agreement:

Legal means shall be provided to prevent use of an indication in a manner that misleads the public or when it constitutes unfair competition, and to invalidate a trademark if the public is misled as to the true place of origin. (Art.22)

Additional protection is conferred on geographical indications for wines and spirits, including ways of protecting homonymous indications. (Art.23)

Negotiations shall be undertaken to establish a multilateral system of notification and registration, aimed at increasing the protection of indications for wines and spirits.(Art.24)

Exceptions to the required protection may be based on prior and continuous use of an indication, prior application or registration in good faith of a trademark, or on the customary use of the indication. (Art.24)

Obligations only relate to geographical indications that are protected in their country of origin. (Art 24)

(d) Industrial Designs (ID)

Section 4, Part II (Article 25 and Article 26) of the TRIPS Agreement contains the provisions for minimum standards in respect of Industrial designs.

Industrial designs are an element of intellectual property. Industrial designs refer to creative activity, which result in the ornamental or formal appearance of a product. Design rights refer to a novel or original design that is accorded to the proprietor of a validly registered design. But it does not include any mode or principle or construction or any thing which is in substance a mere mechanical device.

India has already amended its national legislation to provide for these minimal standards. The essential purpose of the Designs Act, 2000 is to promote and protect the design element of industrial production. It is also intended to promote innovative activity in the field of industries. The present legislation is aligned with the changed technical and commercial scenario and conforms to the international trends in design administration.

Under the Designs Act, the designs would not include any trade mark, as defines in the Trade Marks Act or property mark or artistic works as defined in the Copyright Act.

The duration of the registration of a design is initially ten years from the date of registration, but in cases where claim to priority has been allowed the duration is ten years from the priority date. This initial period of registration may be extended by further period of 5 years on an application before the expiry of the said initial period of

Copyright. The proprietor of a design may make an application for such an extension as soon as the design is registered.

Industrial Design in the TRIPS Agreement:

Protection to new or original designs. (Art.25)

Protection for textile designs through industrial design or copyright law. (Art 25).

Exclusive rights can be exercised against acts for commercial purposes, including importation. (Art 26)

Minimum Term of Protection is ten years. (Art 26)

(e) Patents

Section 5 Part II of the TRIPS Agreement (Article 27 to Article 34) contains the provisions for standards in respect of the Patents.

A Patent is an exclusive right granted by a country to the inventor to make, use, manufacture and market the invention that satisfies the conditions of novelty, innovativeness and usefulness. Members are required to comply with the Paris Convention for the Protection of Industrial Property.

Introduction of Patent Law in India took place in 1856 whereby certain exclusive privileges to the inventors of new inventions were granted for a period of 14 years.

Presently, the patent provisions in India are governed by the Patents Act, 1970. The Indian Patents Act is fully compatible with the TRIPS Agreement, following amendments to it; the last amendment being in 2005 by the Patents (Amendment) Act, 2005.

Product patents in the field of pharmaceuticals and agro-chemicals have been introduced by deleting Section 5 of the Patents Act. Those inventions which are considered a mere discovery of a new form of a known substance or mere discovery of a new property or new use will not be considered patentable. A provision for patenting of software that is embedded in hardware has also been introduced in the Patents Act.

The term of every patent is now for 20 years from the date of filing. Provisions for the pre-grant opposition to the grant of patents have also been incorporated in the Act. Earlier such provisions were available only for post-grant opposition. The filing date of a patent application and its complete specification will now be the international date of filing for the patent as per the provisions of the Patent Cooperation Treaty.

A provision has also been introduced in the Patents Act to enable the grant of compulsory licenses for the export of medicines to countries with limited or no manufacturing capacities to meet emergent public health situations. The law effectively balances and calibrates intellectual property protection with public health concerns and national security. This provision is in line with the Decision of the WTO of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

Patents in the TRIPS Agreement:

Patents shall be granted for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application. No discrimination in respect to place of invention. Exception available for diagnostic, therapeutic and surgical methods of treatment for humans or animals, as well

as plants and animals and essentially biological processes for the production thereof.
(Art.27)

Exclusive right to owners against third party for using subject matter including process of patent, without his consent. (Art 28) Inventions shall be disclosed in a manner, which is sufficiently clear and complete for a skilled person in the art to carry out the invention.
(Art. 29)

Limited exceptions to the exclusive rights provided such exception do not conflict with normal exploitation of the patent. (Art.30)

Revocation/forfeiture is subject to judicial review. (Art 32)

The term of protection shall be at least 20 years from the date of application. (Art.33)

Reversal off the burden of proof in civil proceedings relating to infringement of process patents is to be established in certain cases. (Art.34)

(f) Layout Designs of Integrated Circuits

Articles 35 to 38 of Section 6/Part II of the TRIPS agreement contains the provisions for protection of rights in respect of Layout Designs of Integrated Circuits.

The basis for protecting integrated circuit designs (Topographies) in the TRIPS Agreement is the Washington Treaty on Intellectual Property in Respect of Integrated Circuits, 1989. India is a signatory to this international agreement.

In India, the IPRs on the layout designs of integrated circuits are governed by the Semiconductor Integrated Circuits Layout-Design Act, 2000.

Under this Act, a layout-design shall be considered original if it is the result of its creator's own intellectual efforts and is not commonly known to the creators of layout-designs and manufacturers of semiconductor integrated circuits at the time of its creation. But a layout-design, which is not original, or which has been commercially exploited anywhere in India or in a convention country; or which is not inherently distinctive; or which is not inherently capable of being distinguishable from any other registered layout-design, shall not be registered as a layout-design. But if a layout-design which has been commercially exploited for not more than two years from the date on which an application for its registration has been filed either in India or in a convention country shall be treated as not having been commercially exploited.

The registration of a layout-design shall be only for a period of ten years counted from the date of filing an application for registration or from the date of first commercial exploitation anywhere in India or in any country whichever is earlier. No person shall be entitled to institute any proceeding to prevent, or to recover damages for, the infringement of an unregistered layout-design.

Lay out Design in the TRIPS Agreement:

Protection in accordance with Treaty on Intellectual Property in Respect of Integrated Circuit. (Art.35)

Protection shall extend to layout designs as such and to the industrial articles that incorporate them. (Art.36)

Bona fide purchasers of products involving infringing layout designs shall be liable to pay compensation to the rights- holder after. (Art.37)

Term of protection is a minimum of 10 years notification. (Art 38)

(g) Protection of undisclosed information

Article 39 of Section 7 Part II of the TRIPS agreement elaborates on the protections of trade secrets.

A Trade Secret or undisclosed information is any information that has been intentionally treated as secret and is capable of commercial application with an economic interest. It protects information that confers a competitive advantage to those who possess such information, provided such information is not readily available with or discernible by the competitors. They include technical data, internal processes, methodologies, survey methods used by professional pollsters, recipes, a new invention for which a patent application has not yet been filed, list of customers, process of manufacture, techniques, formulae, drawings, training material, source code, etc. Trade Secrets can be used to protect valuable "know how" that gives an enterprise a competitive advantage over its competitors.

The Agreement provides that natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by or used by others without their consent in a manner contrary to honest commercial practices. Further, parties are required to protect against unfair commercial uses, undisclosed or other data obtained as a condition of approving the marketing of pharmaceutical or of agricultural chemical products.

There is no specific legislation regulating the protection of trade secrets. India follows common law approach of protection based on contract laws.

Trade Secrets in the TRIPS Agreement:

Undisclosed information is to be protected against unfair commercial practices, if the information is secret, has commercial value and is subject to steps to keep it secret.

Secret data submitted for the approval of new chemical entities for pharmaceutical and agrochemical products should be protected against unfair commercial use and disclosure by governments.

- **Issues Under Negotiations in the TRIPS Council of The WTO**

Relationship between TRIPS Agreement and the Convention on Biological Diversity (CBD) and Protection of Traditional Knowledge.

Non-Violation and Situation Complaints.

Additional protection to geographical indications (GIs) to products other than wines and spirits.

Multilateral GI Register for wines and spirits.

(A) TRIPS Agreement and Convention on Biological Diversity (CBD)

Conservation and sustainable use of biological diversity and associated traditional knowledge is critical for meeting the food, health and other needs of the growing world population. Granting of patents on products out of the biological material and processes based on traditional knowledge overlooking the interests of the holders of such biological material and knowledge undermines the prospects of conservation and sustainable use of genetic resources and associated traditional knowledge. A number of developing countries, including the group of Mega-diverse countries, have consistently argued that bio-piracy and misappropriation seriously affect the developmental benefits, environmental benefits, and the economic benefits of the people who are holders of biological material and associated traditional knowledge.

The Doha Ministerial Declaration in paragraph 19 provided a mandate to the TRIPS Council for " pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, 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."

India and other developing countries have been raising the issue of protection of traditional knowledge and the relationship between the CBD and the TRIPS Agreement for the last few years in the WTO. To take the discussions forward on the above mentioned issues and also to fulfill the mandate contained in Para 19 of the Doha Ministerial Declaration, a number of developing countries submitted in the TRIPS Council (IP/C/W/420) that an applicant for a patent, who uses genetic resources and/or traditional knowledge associated with that, shall as a condition ("disclosure requirements") for acquiring patent rights provide the following:

Evidence of Disclosure of source and country of origin of the biological resource and/or associated traditional knowledge used in the invention;

Evidence of prior informed consent (PIC) under the relevant national regime; and

Evidence of benefit sharing under the relevant national regime.

Disclosure of Source and Country of Origin

India along with other developing countries submitted a paper (IP/C/W/429/Rev.1) in September 2004 suggesting elements of the obligations on the first of the three issues i.e. disclosure of source and country of origin and traditional knowledge used in the invention (disclosure obligation).

This disclosure obligation would help in better examination of patents and in preventing cases of bad patents. It would also be useful in cases relating to challenges to the grant of patents or disputes on inventorship or entitlement to a claimed invention as well as infringement cases. Article 29 of the TRIPS Agreement already enjoins upon Members to require that patent applicants disclose the invention in a manner sufficiently clear and

complete for the invention to be carried out by a person skilled in the art. This is to ensure the quality of patents as well as to ensure transparency. Likewise, the disclosure of source and country of biological resources and /or traditional knowledge used in an invention would play a critical role in ensuring patent quality.

Insufficient, wrongful or lack of disclosure, if discovered after the grant of a patent, would invite legal sanctions, including revocation of a patent where it is determined that the proper disclosure would have led to the refusal to grant the patent either on the grounds of lack of novelty due to the existence of prior art or on the grounds of order public or morality and where the intention is fraudulent. The burden of proof, therefore, would lie on the applicant to establish that the genetic resource and/or traditional knowledge was legally and legitimately accessed and that benefit sharing had or would take place if a patent is granted with respect to the invention that used such genetic resources and/ or traditional knowledge.

Evidence of Prior Informed Consent (PIC)

India along with some developing countries submitted another paper (IP/C/W/438) in December, 2004 on the second issue of the checklist, i.e. elements of the obligations to disclose evidence of prior informed consent under the relevant national regimes.

Access to genetic resources is important to researchers and bio-prospectors. Likewise, Prior Informed Consent by providers of these resources and arrangements for fair and equitable benefit sharing are important for bio-diversity rich countries and local and indigenous communities. The requirement will reduce the probability and cost of litigation on validity or entitlement to the patent.

Mandatory furnishing of evidence of PIC by patent applicants in the form of additional information in patent applications would facilitate fulfillment of requirement under Article 15 of CBD. The route through contractual arrangement, as was suggested by some WTO members, to achieve PIC is not viable, because there is no obligation on this

issue in international law, at least not in all countries, particularly those which are not Members of the CBD.

Contractual arrangements alone cannot suffice to ensure the monitoring and enforcement of the requirements of the CBD in third countries. Contractual arrangements cannot be relied upon when traditional or indigenous communities who are often illiterate and unorganized are to bargain with MNCs. This could be provided for by enjoining upon the Members to require, as a condition for acquiring patent rights, that applicants furnish evidence of PIC with respect to access to genetic resources and/or traditional knowledge used in the invention. This requirement would be fully compliant with the existing relevant provisions of TRIPS Agreement including Article 62.1. This requirement would not impose a cumbersome or unreasonable burden on applicants.

The applicant will be deemed to have complied with this requirement, if the patent application contains and /or is accompanied by a declaration, in the prescribed form, indicating that PIC was obtained from the relevant national authorities and local and indigenous communities, where applicable. The declaration would be accompanied by the actual evidence of PIC, in the form of a certificate or duly certified contract between the applicant and the national authorities of the country of origin. A single declaration with the necessary evidence could also be furnished to cover the requirements on disclosure of source and country of origin, evidence of PIC as well as evidence of equitable benefit sharing. This requirement could largely be met by having a single additional column in the patent applications for the applicant to declare the above by attaching a certificate or other instrument.

In case a member does not have a national access regime or competent authority to grant PIC, the applicant would be deemed to have complied with the obligation by indicating in the relevant declaration that there was no national regime in the country of origin and there was consent, at least, from the authority or community in charge of the location where the genetic resources and/or traditional knowledge was accessed.

There would be separate and additional legal effect associated with enforcing obligations related to PIC. At the pre-grant stage, the legal effect could be that the application would not be processed any further till necessary declaration and evidence are furnished. There could be penalties and time limits to submit the declaration and evidence, otherwise the application could be deemed withdrawn. At the post-grant stage, the legal effect could be revocation of patent and /or criminal and /or civil sanctions including the possibility of punitive damages.

Evidence of Access and Benefit Sharing (ABS)

Submission (IP/C/W/442) on the third element of the checklist, namely, on the elements of obligations associated with regard to benefit sharing was made by India in March 2005. The framework within which to determine the terms of EBS could be as prescribed in the CBD. The requirement of this element would operate as a vital supplementary measure and a necessary incentive for patent applicants to comply with the laws of the country of origin of the GR and/or TK in accordance with the objectives of the CBD.

Establishment of a mechanism at the national level alone is not sufficient, because action by patent offices in one country to prevent bio-piracy does not ipso facto lead to similar actions in other countries, and so the establishment of an international framework of protection is needed. Under such a system, there would be a procedure for allowing access to and use of genetic resources and/or associated traditional knowledge, especially for its commercial exploitation, only after the country of origin certifies that prior informed consent and benefit sharing conditions have been accepted. An ideal patent system would be supportive to the objectives of such a framework. This disclosure can ideally be made at the time of applying for a patent.

If the country of origin does not have domestic laws for such disclosures, a patent applicant will be deemed to have complied with the international obligation by indicating so in the application and that benefit sharing arrangement with the community in charge of accessed genetic resources and/or the traditional knowledge have been made in accordance with the prevailing laws. Legal effect of willful non-compliance will lead to

an automatic moratorium on the processing of such applications until such evidence is provided. This could also be accompanied with penalties including criminal penalties and time-limits for compliance beyond which the application will be deemed withdrawn. If non-compliance is noticed after the grant, legal effect could lead to revocation of the patent; criminal and/or civil sanctions outside the patent system, including the possibility of punitive damages.

Current Access & Benefit Sharing system in India

The access to genetic resources and subsequent sharing of benefits in India is regulated by the Biological Diversity Act, 2002. The Act provides for conservation of biological diversity, sustainable use of its components, and fair and equitable sharing of the benefits arising out of the utilization of biological resources, knowledge and matters incidental to them. Under the Act, traditional knowledge associated with genetic resources also forms a part of the access framework.

The Biological Diversity Act provides that non-Indians, non-resident Indians and foreign companies not involved with collaborative research projects have to obtain approval of the National Biodiversity Authority for undertaking any activities in relation to biological resources or knowledge associated thereto. The Indian citizens or body corporates have to inform the State Biodiversity Board about the same.

Position of some developed countries on the TRIPS-CBD Relationship

Objectives of the TRIPS Agreement and the CBD are distinct and there is no conflict between them.

Provisions regarding disclosure of source of biological resources and evidence of PIC and benefit sharing are neither necessary nor desirable for implementing the PIC and benefit sharing provisions of the CBD, and would be unnecessarily burdensome. It is not easy to determine with certainty the origin of the biological resources.

These obligations would increase costs of acquiring patents. It could also encourage inventors to keep their inventions secret rather than apply for patents and come into public domain.

The proposed obligations are not consistent with TRIPS Agreement. Existing disclosure requirement under Article 29 of TRIPS Agreement are directly related to determining whether an invention meets the standards of patentability and disclosure of technology to enable others skilled in the art to reproduce the invention. Proposed obligations would also be contrary to Article 27.1 which provides for non-discrimination in patent availability among fields of technology.

Intellectual Property Rights do not aim to regulate the access and use of genetic resources. This could best be done through contracts between the authorities competent for granting access to genetic resources and/or traditional knowledge and those intending to make use of such resources and traditional knowledge.

In accordance with the provisions of the CBD, countries could incorporate in their national legislation requirements for the conclusion of such contracts and the terms and conditions under which access and use may be granted including provisions for transfer of technology that might result from such use of genetic resources and/or traditional knowledge to which access is to be granted. Criminal and /or Civil remedies could also be provided for in the event of breach of obligations on either side and contracts can be litigated in the specified jurisdiction and judgements passed thereon could be enforced around the world under international agreements on recognition of judgements.

Disclosure requirement in the patent applications with regard to evidence of PIC will not prevent misappropriation.

Disclosure requirement with regard to evidence of benefit sharing can not transfer benefits because such requirement would merely convey the information required. It would have no mechanism to transfer benefits between parties.

If the country of origin and /or traditional knowledge has no benefit sharing infrastructure in place for the use of biological resources and/or traditional knowledge, any compensation to the custodians of such resources and/or traditional knowledge would not be possible even if a patent relates to these materials. So, first a mechanism to transfer benefits must be established.

A new disclosure requirement could have significant, unintended consequences. For example, if improper disclosure results in revocation of a patent due to litigation by a third party which is not affiliated with a biological resources and/or traditional knowledge, this could actually upset the benefit-sharing agreement arrived at before grant of the patent.

If an inventor fails to get patent on an invention which is associated with biological resources and /or traditional knowledge because of his inability to properly fulfill disclosure requirements or even if a patent is granted but later it is revoked owing to wrongful disclosure, the inventor may still be able to commercialize the invention outside the patent system without disclosing the invention to the public and without any obligation to share benefits. In either case, the invention having been disclosed to the public, third parties are most likely to use and commercialize the resources and/or traditional knowledge so disclosed without any obligation of sharing benefits.

The disclosure requirements will be ineffective in having a better assessment by patent examiners of novelty and inventive step; rather these would only complicate an already overburdened patent system.

New patent disclosure requirement may lead to significant administrative burdens for the patent offices of Member countries that would in turn create additional costs, with regard to those requirements which demand compliance with foreign laws.

It does not seem possible that patent examiners could examine, with legal certainty, decisions involving interpretations of foreign laws to determine the validity of PIC or benefit sharing. This would only compound the uncertainties both in granted patent rights and in the process of granting patents.

Hong Kong Ministerial Conference

During the Hong Kong Ministerial Conference, the Ministers reiterated the following in Para 39:

"We reiterate the instruction in the Decision adopted by the General Council on 1 August 2004 to the TNC, negotiating bodies and other WTO bodies concerned to redouble their efforts to find appropriate solutions as a priority to outstanding implementation-related issues. We take note of the work undertaken by the Director-General in his consultative process on all outstanding implementation issues under paragraph 12(b) of the Doha Ministerial Declaration, including on issues related to the extension of the protection of geographical indications provided for in Article 23 of the TRIPS Agreement to products other than wines and spirits and those related to the relationship between the TRIPS Agreement and the Convention on Biological Diversity. We request the Director-General, without prejudice to the positions of Members, to intensify his consultative process on all outstanding implementation issues under paragraph 12(b), if need be by appointing Chairpersons of concerned WTO bodies as his Friends and/or by holding dedicated consultations. The Director-General shall report to each regular meeting of the TNC and the General Council. The Council shall review progress and take any appropriate action no later than 31 July 2006."

Post-Hong Kong Development

India along with other developing countries has demanded inclusion of "disclosure requirements" in the patent applications. For that a proposal to amend the TRIPS Agreement (by inserting Article 29bis) was submitted to the Trade Negotiations Committee (TNC) and to the General Council on 31st May 2006. This proposal is in line with the mandate of the Hong Kong Ministerial Conference. The text for the proposed Article 29bis takes into account the objectives of the requirement as well as the questions, comments and concerns raised by various Members in the negotiations so far.

Proposed Article 29bis in the TRIPS Agreement

Disclosure of Origin of Biological Resources and/or Associated Traditional Knowledge

For the purposes of establishing a mutually supportive relationship between this Agreement and the Convention on Biological Diversity, in implementing their obligations, Members shall have regard to the objectives and principles of this Agreement and the objectives of the Convention on Biological Diversity.

Where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge, Members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin. Members shall also require that applicants provide information including evidence of compliance with the applicable legal requirements in the providing country for prior informed consent for access and fair and equitable benefit-sharing arising from the commercial or other utilization of such resources and/or associated traditional knowledge.

Members shall require applicants or patentees to supplement and to correct the information including evidence provided under paragraph 2 of this Article in light of new information of which they become aware.

Members shall publish the information disclosed in accordance with paragraphs 2 and 3 of this Article jointly with the application or grant, whichever is made first. Where an applicant or patentee provides further information required under paragraph 3 after publication, the additional information shall also be published without undue delay.

Members shall put in place effective enforcement procedures so as to ensure compliance with the obligations set out in paragraphs 2 and 3 of this Article. In particular, Members shall ensure that administrative and/or judicial authorities have the authority to prevent the further processing of an application or the grant of a patent and to revoke, subject to

the provisions of Article 32 of this Agreement, or render unenforceable a patent when the applicant has, knowingly or with reasonable grounds to know, failed to comply with the obligations in paragraphs 2 and 3 of this Article or provided false or fraudulent information.

Many countries have supported this approach of text-based negotiations. Norway proposed on 13th June 2006 that there was a need to amend the TRIPS Agreement by inserting Article 29bis, and start negotiations on the subject.

(b) Non-Violation and Situation Complaints

General Overview

Disputes can be initiated under the WTO, like in many other legal systems, when there is a specific violation of a rule or law. The General Agreement on Tariffs and Trade (GATT), applicable to the WTO's Dispute Settlement Understanding (DSU), provides for a further category of disputes - commonly referred to as Non-Violation and Situation Complaints.

The basic principles of a Non-Violation complaint are laid out under Article XXIII(1)(b) of the General Agreement on Tariffs and Trade, 1994. This provision provides for a procedure for a complaint to be set into motion when a Member country considers that a benefit under the WTO Agreements, accruing to it directly or indirectly, is nullified or impaired as a result of another Member country applying a measure, irrespective of whether or not such measure conflicts with any of the WTO Agreements. Article XXIII(1)(c) extends such nullification or impairment as resulting from a broader range of circumstances, captured by the phrase 'existence of any other situation'. This clause is normally referred to as a 'situation complaint'.

Both these circumstances envisaged were generally felt to be very broad. Streamlining of the procedural aspects for exercise of the same is sought to be achieved to a certain extent under Article 26 of the Dispute Settlement Understanding (DSU) of the WTO. Article 26 specifies certain procedural requirements for initiating a non-violation complaint under

Article XXIII(1)(b). This includes, inter alia, that where a measure is found to nullify or impair benefits under the WTO, without a violation of the same, there is no obligation to withdraw the measure. However, a Panel or Appellate Body of the WTO can recommend to the Member to make a mutually satisfactory arrangement. The DSU also provides that an arbitration panel may be constituted to examine the level of benefits alleged to have been nullified or impaired, and suggest ways and means for reaching a mutually satisfactory arrangement. These suggestions, however, are not legally binding on the Member(s).

TRIPS Agreement and Non-Violation Complaints

Both Article XXIII(1)(b) and Article XXIII(1)(c) of the GATT are referred to in Article 64 of the TRIPS Agreement, which establish a moratorium on the application of the non-violation remedy to the Agreement, and commits WTO Members to examine how the concept might apply in the context of the TRIPS Agreement. The moratorium under Article 64 was specified only till January 2000.

The Doha Decision on Implementation-Related Issues and Concerns instructs the TRIPS Council to make a recommendation to the Cancún Ministerial Conference. Until then, members agreed not to file non-violation complaints under TRIPS.

In May 2003, the TRIPS Council Chairperson listed four possibilities for a recommendation:

- banning non-violation complaints in TRIPS completely,
- allowing the complaints to be handled under the WTO's dispute settlement rules as applies to goods and services cases,
- allowing non-violation complaints but subject to special "modalities" (i.e. ways of dealing with them), and
- extending the moratorium.

In response, most members favoured banning non-violation complaints completely, or extending the moratorium. However, no consensus was reached at that time. The 1

August 2004 General Council decision (the "July 2004 package") extended the moratorium to the Hong Kong Ministerial Conference.

In the Hong Kong Ministerial Conference, the Ministers took "note of the work done by the Council for Trade-Related Aspects of Intellectual Property Rights pursuant to paragraph 11.1 of the Doha Decision on Implementation-Related Issues and Concerns and paragraph 1.h of the Decision adopted by the General Council on 1 August 2004, and direct it to continue its examination of the scope and modalities for complaints of the types provided for under subparagraphs 1 (b) and 1 (c) of Article XXIII of GATT 1994 and make recommendations to our next Session.

(b) Additional protection to Geographical Indications (GIs) to products other than wines and spirits.

Introduction

Doha Ministerial Declaration attached the utmost importance to the issue of extension of the protection of geographical indications provided for in Article 23 of the TRIPS Agreement to products other than wines and spirits (referred to as "GI-extension"). By confirming its nature as an outstanding implementation issue, they declared that negotiations on the "GI -extension" shall be an integral part of the Doha Work Programme.

In the decision on the Doha Work Programme adopted by the General Council on 1 August 2004, the Council requested the Director-General to continue with his consultative process on all outstanding implementation issues under paragraph 12(b) of the Doha Ministerial Declaration, including on issues related to the extension of the protection of geographical indications provided for in Article 23 of the TRIPS Agreement to products other than wines and spirits, if need be by appointing Chairpersons of concerned WTO bodies as his Friends and/or by holding dedicated consultations. The Director-General was asked to report to the TNC and the General Council no later than May 2005. The General Council was to review progress and take any appropriate action no later than July 2005.

The Hong Kong Ministerial Conference has mandated to intensify the consultative process on the issue and has instructed the General Council of the WTO to review the progress and take appropriate action no later than 31st July 2006

"Friends of GI"

Many developed and developing countries including India have been demanding the removal of the disparity between two types of protection for GIs for wines and spirits, on the one hand, and all other products, on the other. They have been demanding an expansion of the scope of protection available under Article 23 of the TRIPS Agreement to products other than wines and spirits. The basic idea behind seeking extension of Article 23 protection to all other products, is that GIs can be used to promote the export of valuable products and prevent misappropriation.

India, which is a member of the "Friends of GI" group (which also includes, Switzerland, the EU, Bulgaria, the Czech Republic, Hungary, Sri Lanka, etc.) has been proposing for higher level of protection as provided under Article 23 of TRIPS Agreement to Geographical Indications of products other than wines and spirits. The proposal from the "Friends of GI" group is as under (IP/C/W/353);

the protection of Article 23 of TRIPS Agreement shall apply to geographical indications for all products;

the exceptions contained in Article 24 of the TRIPS Agreement shall apply mutatis mutandis; and

the multilateral register to be established shall be open for geographical indications for all products.

The US, Australia, Argentina, Canada, Chile and some other Latin American countries have expressed their reservations against the proposal. The main arguments against the above proposal are as under (IP/C/W/360);

- (i) The benefits of such extension would accrue to those WTO Members with many geographical indications protected under formal registration system. The burden would fall on those Members with few geographical indications;
- (ii) Article 22 provides sufficient protection but has not been used by the demandeurs;
- (iii) Extension would involve substantial costs.

Frequently Asked Questions on GI-extension

What is the advantage to India in GI-extension?

India is in favour of extension of additional protection of GIs as this would result in obtaining higher level of protection to Indian GIs such as Basmati rice, Darjeeling tea, Assam tea, Nilgiri tea, and also non-agricultural products, such as Pochhampalli Ikat, Chanderi Sarees, Katpad Handloom fabric, Kanchipuram Silk, Mysore Agarbatti, etc. The higher level of protection to Indian GIs would help in bringing higher price realization to our farmers and artisans, besides increased market access.

What is the goal of "GI-extension"?

The goal of "GI-extension" is to increase the legal certainty of the protection that the TRIPS Agreement currently affords to geographical indications on wines and spirits. All WTO Members, and especially the developing countries, are likely to benefit if the more effective protection is afforded not only to geographical indications for wines and spirits but also to all other products.

What are the benefits of "GI-extension"?

By increasing the level of legal certainty and transparency in the international regulatory framework for the protection of geographical indications, "GI-extension" will enhance and benefit international trade flows. Today, the applicable protection regime to geographical indications for non-wine and non-spirit products is based on unclear and ambiguous rules.

Will "GI-extension" result in administrative costs and burden for Members?

No. "GI-Extension" does not require Members to introduce or establish a new legal or administrative protection regime at the national level. Nor does Article 23.1-3 of the TRIPS Agreement require Members administrations and public authorities to enforce "ex officio" the protection of geographical indications against usurpation and free-riding. As for any other intellectual property right and as today for geographical indications for wines and spirits, this is the responsibility of the right holder and legitimate users of a geographical indication.

How about costs to producers?

"GI-extension" will save litigation costs to legitimate producers of GI products through an easier burden of proof in enforcement procedures to end usurpation and illegitimate use of a geographical indication.

And consumers?

"GI-extension" neither attempts to eliminate competition nor intends to erect barriers to trade. No product will be excluded from trade by "GI-extension". On the contrary, "GI-extension" seeks fairer international trade and competition by ensuring a better and more effective regulatory framework for the protection of geographical indications and therewith a use of geographical indications which will benefit both producers and consumers.

"GI-extension" will increase consumers' choice by providing, through a more reliable international protection, an incentive for producers, in particular SMEs, to invest in the production of more GI-products which owe their particular quality, reputation or other characteristic to their geographical origin. Furthermore, "GI-extension" will benefit consumers by providing them with more reliable information about the origin of products using a geographical indication, assisting them thereby in their choice whether they want to pay a premium for the authentic GI-product or opt for a product without the added value of a specific "local flavour".

- **TRIPS And Public Health**

Recognizing the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, Doha Ministerial Conference made a Declaration on the TRIPS Agreement and Public Health giving directions to the TRIPS Council to find a solution to this problem, particularly for those WTO Members, especially Least Developed Countries (LDCs), who do not have manufacturing capacities in the pharmaceutical sector. Ministers also underscored the countries' ability to use the flexibilities that are built into the TRIPS Agreement, in particular compulsory licensing and parallel importing, and they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016. On one remaining question, they assigned further work to the TRIPS Council - to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can import patented drugs made under compulsory licensing. This is sometimes called the "Paragraph 6" issue, because it comes under that paragraph in a separate Doha declaration on TRIPS and health.

The issue arises because Article 31 (f) of the TRIPS Agreement states that products made under compulsory licensing must be "predominantly for the supply of the domestic market". This applies directly to countries that can manufacture drugs - it limits the amount they can export when the drug is made under compulsory licence. And it has an indirect impact on countries unable to make medicines - they might want to import generics made in countries under compulsory licence, but find that Article 31 (f) poses an obstacle to other countries supplying them. the TRIPS Council was instructed to find a solution and report to the General Council on this by the end of 2002. However it was not until 30 August 2003 that consensus could be reached.

After deliberations, the Members arrived at a decision which was adopted by the General Council of the WTO in its meeting held on 30 August, 2003. The Decision is contained in WTO document [WT/L/540](#). It provides waivers from the obligations of Article 31 (f) and Article 31 (h) of the TRIPS Agreement, i.e. a compulsory licence may be issued not only

for predominantly domestic use, but it can also be issued to the extent necessary for the purposes of production of a pharmaceutical product and its export to such countries that have insufficient manufacturing capacity, subject to certain conditions. Para 11 of the document [\(WT/L/540\)](#) stipulates that this Decision, including the resultant waivers granted, would remain operative for a Member till the date on which an amendment to the TRIPS Agreement, replacing its provisions takes effect for that Member. It was also enjoined upon the Council for TRIPS to work on the preparation of such an amendment in the TRIPS Agreement based on the Decision.

After deliberations in the Council for TRIPS, a decision was taken in the General Council about the amendment to the TRIPS Agreement, which is contained in WTO document number [WT/L/641](#) dated 8 December, 2005. This document was later adopted at the Hong Kong Ministerial Conference of the WTO. India has accepted the Protocol amending the TRIPS Agreement, and notified the same to the WTO ([WT/LET/572](#)) on 26th March 2007

The Patents (Amendment) Act, 2005 has already made provisions for taking advantage of the waiver arising out of the General Council Decision of 30 August, 2003.

- **Submissions By India On TRIPS Issues**

- (a) **Transfer of Technology**

Document	Date	Title
WT/GC/W/352	11 - 10 - 1999	Preparations for the 1999 Ministerial Conference
IP/C/W/195	12 - 7 - 2000	Communication from India
IP/C/W/196	12 - 7 - 2000	Communication from India

- (b) **Protection of Biodiversity and Traditional Knowledge**

Document	Date	Title
IP/C/W/161	3 - 11 - 1999	Review of the Provisions of Article 27.3(B)

IP/C/W/195	12 - 7 - 2000	Communication from India
IP/C/W/196	12 - 7 - 2000	Communication from India
IP/C/W/198	14 - 7 - 2000	Protection of Biodiversity and Traditional Knowledge – The Indian Experience
IP/C/W/356	24 - 6 - 2002	The Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge
IP/C/W/403	24 - 6 - 2003	The Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge
IP/C/W/420	2 - 3 - 2004	The Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD)
IP/C/W/429/Rev.1	27 - 9 - 2004	Elements of the obligation to Disclose the Source and Country of Origin of the Biological Resources and/or Traditional Knowledge used in an Invention
IP/C/W/438	10 - 12 - 2004	The Relationship Between the TRIPS Agreement And the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge-Elements of the obligation to Disclose Evidence of Prior Informed Consent under the Relevant National Regime
IP/C/W/442	18 - 3 - 2005	The Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge – Elements of the Obligation to Disclose Evidence of Benefit-Sharing under the Relevant National Regime
IP/C/W/443	18 - 3 - 2005	The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge Technical Observations on Issues Raised In A Communication by the United States (IP/C/W/434)
IP/C/W/459	18 - 11 - 2005	The Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge Technical observations on the United States Submission IP/C/W449 by Bolivia, Brazil, Colombia, Cuba, India And Pakistan
IP/C/W/470	21 - 3 - 2006	Submission in Response to the Communication

		from Switzerland (IP/C/W/446)
WT/GC/W/564	31 - 5 - 2006	Doha Work Programme – The Outstanding Implementation Issue on the Relationship between the TRIPS Agreement and the Convention on Biological Diversity

(c) Extension of additional protection for geographical indications to products other than wines and spirits

Document	Date	Title
IP/C/W/204 /Rev.1	2 -10 - 2000	Communication from Bulgaria, the Czech Republic, Egypt, Iceland, India, Kenya, Liechtenstein, Pakistan, Slovenia, Sri Lanka, Switzerland and Turkey.
IP/C/W/247/Rev.1	17- 5 - 2001	Proposal from Bulgaria, Cuba, the Czech Republic, Egypt, Iceland, India, Jamaica, Kenya, Liechtenstein, Mauritius, Nigeria, Pakistan, Slovenia, Sri Lanka, Switzerland, Turkey and Venezuela.
WT/GC/W/540/Rev.1	14 -12 -2004	Doha Work Programme – The Extension of the Additional Protection for Geographical Indications to Products other than Wines and Spirits
IP/C/W/308/Rev.1	2 - 10 - 2001	Communication from Bangladesh, Bulgaria, Cuba, The Czech Republic, Georgia, Hungary, Iceland, India, Jamaica, Kenya, The Kyrgyz Republic, Liechtenstein, Moldova, Nigeria, Pakistan, Slovenia, Sri Lanka, Switzerland and Turkey.
IP/C/W/353	24 - 6 - 2002	Communication from Bulgaria, Cuba, Cyprus, The Czech Republic, The European Communities and Their Member States, Georgia, Hungary, Iceland, India, Kenya, Liechtenstein, Malta, Mauritius, Pakistan, Romania, The Slovak Republic, Slovenia, Sri Lanka, Switzerland, Thailand and Turkey.

(d) TRIPS and Public Health

Document	Date	Title
IP/C/W/296	29 - 6 - 2001	Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Domi Nican Republic, Ecuador, Honduras, India, Indon Esia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand And Venezuela.
JOB(01)/97/Add9	2 - 7 - 2001	Intellectual Property and Access to Medicines
IP/C/W/355	24 - 6 - 2002	Paragraph 6 of the Ministerial Declaration on The TRIPS Agreement And Public Health

(e) Non-Violation and Situation Nullification or Impairment

Document	Date	Title
IP/C/W/385	30 -10 -2002	Non-Violation and Situation Nullification or Impairment under the TRIPS Agreement

• Important Submissions by other Members

a) Protection of Biodiversity and Traditional Knowledge

Document	Date	Title
IP/C/W/434	26 -11-2004	Article 27.3(B), Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore
IP/C/W/441	8 - 3 - 2005	Article27.3(B), Relationship between the TRIPS Agreement and the CBD And Protection of Traditional Knowledge and Folklore
IP/C/W/446	30 - 5 - 2005	The Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) And The Protection of Traditional Knowledge and Folklore and the Review of Implementation of the TRIPS Agreement under Article 71.1
IP/C/W/449	10 - 6 - 2005	Article 27.3(B), Relationship between the TRIPS

		Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore
IP/C/W/473	14 - 6 - 2006	The Relationship between the TRIPS Agreement, the Convention on Biological Diversity and the Protection of Traditional Knowledge Amending the TRIPS Agreement to Introduce an Obligation to Disclose the Origin of Genetic Resources and Traditional Knowledge in Patent Applications

b) Extension of additional protection for Geographical Indications to products other than wines and spirits

Document	Date	Title
IP/C/W/360	26 - 7 - 2002	Implications of Article 23 Extension