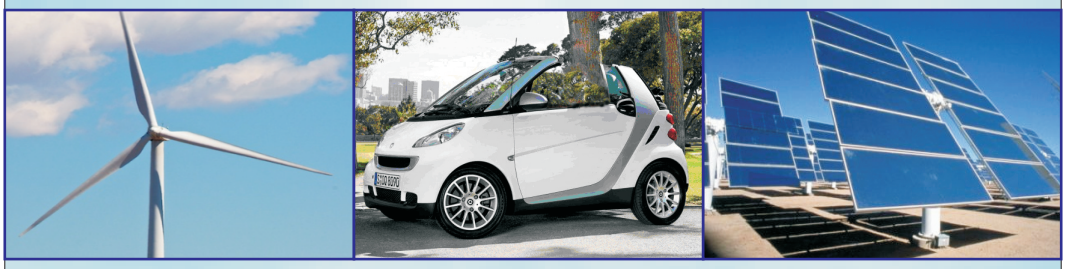
FAQ

Frequently
Asked
Questions

Transfer of Technology in Environmentally Sound Technologies



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Preface

The developing countries realise that Climate Change related adaptation and mitigation measures would have significant impact on their economy and affect their growth potential. Hence, to pursue sustainable development path they seek access to technology in context of cutting-edge environmentally sound technologies (ESTs) required for adapting to, as well as for mitigating climate change. It is important to understand the requirements of the developing countries and understand how their perspective differ from that of the developed countries in this regard. This would help the reader develop a better understanding of the issues involved and appreciate the changes that may be required to give the developing countries access to green technologies. This publication attempts to give a brief snapshot of the issues involved and suggests suitable mechanism through which the ESTs could be transferred.

This publication draws on the initial analysis done by officers of Department of Commerce, Government of India in their individual capacity and does not reflect the official views of the Government of India. We are also thankful to Mr. Nitya Nand, Convenor, TERI for his valuable comments on the contents. Views and comments of readers are welcome and may be sent at **editor_wtocentre@iift.ac.in**

Chapter Index

Chapter 1

Developed Country versus Developing Country Perspective

Q1. What is transfer of technology (TOT)?

A1. Technology transfer is a broad set of processes, covering the transfer of technology, together with the know-how, experience and equipment in order to effectively implement/ use/ diffuse the technology in the recipient economies. In case of Environmentally Sound Technologies (**ESTs**), it covers technologies required for climate change mitigation and adaptation as well as other pollution control measures.

Q2. What is the perspective of developing countries regarding ESTs?

A2. The developing countries view the green technologies as **global public goods.** Hence, they hold that ESTs should not be encumbered by various impediments, including the IP regime, which impedes TOT. To undertake climate change mitigation and adaptation measures, the developing countries perceive that the access to cutting edge clean energy technologies is essential due to the following reasons:

(i) To diversify energy sources and reduce carbon emissions in a cost effective manner.

(ii) To accelerate innovation in technology development, deployment, adoption, diffusion and transfer of ESTs. This would help them conceive cost-effective

technologies built on local materials that best suit their local needs, and diffuse them.

(iii) To reduce the current disadvantage they face vis-à-vis the developed countries in the international trade of EGs. The developing countries perceive that this would help address the mandate of the WTO's Doha Declaration that the effect of environmental measures on market access in relation to developing countries is kept in view.

(iv) To generate financial surplus for sustainable development through an enhanced share in international trade.

The developed countries should owe historical responsibility for the current climate crisis and help facilitate the process of addressing climate change (**CC**) concerns by agreeing to transfer technology, and helping developing countries build capacity in this area. The developed countries should also provide adequate financial assistance to address climate change adaptation and mitigation needs.

Q3. What are the problems that the developing countries foresee regarding TOT in ESTs?

A3. Contrary to popular belief, globalization has not resulted in much dissemination and TOT. While transnational corporations are decentralizing operations such as production and sourcing internationally, the R&D activities are not sufficiently internationalized. Despite globalization and spread of some R&D activities into developing countries, associated technology has remained highly centralized in industrialized countries. The developing countries perceive the following specific problems in regard to TOT:

(i) Intellectual property rights (**IPRs**) prohibit access to new technologies by enabling firms that own patented technologies to keep prices prohibitively high.

(ii) IPR monopolist often refuses to sell/ license such technology fearing competition from low cost manufacturing in developing countries.

(iii) Financial advantages that accrue to technological first movers encourage them to enter into "strategic alliances" even with potential competitors to share market and prevent/ impede TOT to developing countries.

(iv) Technology not protected by specific patents is also expensive depending on the various equipments and human resources for enabling effective access to such EFTs.

(v) Even while transferring technologies the owners may not transfer the related know-how and experience required to effectively exploit the technology.

Q4. What is the perspective of the developed countries in the context of TOT?

A4. The developed countries hold that technologies are held by private companies on which they have little control. The following factors impede the TOT to developing countries by such private companies:

(i) Lack of sufficient IP protection in developing countries disincentivises patent holders from licensing technologies into developing country markets.

(ii) Dilution of patent regime on ESTs would discourage investments in R&D.

(iii) Relaxation of IP regime could lead the technology owners to protect them as trade secret.

(iv) Even if the IP regime is relaxed, the developing countries may not have the manufacturing capacity and the know how to use such technologies.

The developed countries hold that a strong patent regime creates incentives for investment in R&D activities and would enhance the confidence of the licensor firms that proprietary technology will not leak into the host economy through copying or defection of personnel.

Q5. How justified is the view of the developed countries as brought out in A4 above?

A5. The perception of the developed countries may not entirely be correct for following reasons:

(i) Although the IP regime (substantive provisions and their enforcement) of the developing countries is compliant with the WTO's TRIPS Agreement requirements, not much TOT has taken place.

(ii) While the IP protection definitely creates incentives for R&D investment, the inventors are not always lured by financial incentives; there are other reasons such as the love for creation, fame and altruistic ambitions that drive them.

(iii) Developing countries are often willing to pay reasonable compensation to patent holders.

(iv) Trade secret is not the best mode of protection and makes the technology susceptible to reverse engineering. Had trade secret been secure enough, the patent type of IP protection that lapses after a stipulated period would not have been visualised.

(v) The developing countries may not currently be having manufacturing capacity in all sectors or may be lacking the experience to make effective use of them. But it is a chicken and egg situation: if the technology remains restricted the necessary capacities and experience may never be generated.

(vi) In the developed countries, such as the US and EU, the research efforts in ESTs are often subsidized by Government grants. This confers an undue advantage to manufacturers of such ESTs in these countries. Hence, developing countries have a justified case to seek subsidized access to such technologies.

Q6. How do the developed countries view the comparison of the ESTs vis-a-vis medicine technologies?

A6. In the context of establishing an effective TOT regime in ESTs, the developing countries often cite the Doha Declaration on Public Health, 2001 that set in a process to allow access to patented medicines through compulsory licensing. However, the developed countries hold that the concerns of developing countries about patents on ESTs are built on wrong comparison with medicine technologies since ESTs are radically different from medicine technologies. The patent premium on medicines makes up a significant portion of the final price because the cost of initial research is large and the physical manufacture cost of medicines is relatively small. Also, medicines are built on single-compound patents that often turn the exclusive right conferred by a patent into a near-monopoly, because of the lack of competition from other products that can provide the same therapeutic outcome. In ESTs, unlike medicines, the physical cost and tacit knowledge in manufacture and deployment make up the vast majority of the final product's cost. Also, because there is significant

inter- and intra-product competition, the leveraging capacity of a patent in case of ESTs, is relatively modest. For example, if a wind turbine manufacturer sells an expensive product there are plenty of other competitor technologies, as well as other wind turbine manufacturers, to keep the price down. The basic ESTs are now already off-patent. Further, the developed countries hold that in cases where patents are not registered in the developing countries, the latter are free to use these technologies.

However, the developed countries, in particular the US, EC and Japan, where most of the cutting edge ESTs are patented, strongly resisted any reference to IPRs in context of TOT negotiations in the Dec'09 Copenhagen UNFCCC negotiations. This clearly conveys that the IPRs are not as unimportant.

Q7. Is the viewpoint of the developed countries entirely justified?

A7. In the renewable energy sector the basic approaches to solving specific technological problems are now off patent - the basic ESTs, such as solar photovoltaic cell and wind power are already in public domain. However, the cutting edge technologies that would enable more efficient energy conversion, provide higher capacity, reduce break-downs through use of critical components, etc. remain patented. Such technologies are must for making renewable energy economical for mass scale use in developing countries. Further, for making effective use of potential technologies, such as geo thermal energy, tidal energy, improved energy transmission materials, sea water desalination to improve water availability for irrigation purposes, etc., developing countries need cutting edge technology.

Q8. What are the views of the developing countries in context of trade liberalisation on environment goods (EGs)?

A8. The trade liberalisation on EGs is being negotiated in the Doha round of the WTO. The developed countries advocate that liberal import of EGs by the developing countries could help the latter better address environment concerns. The developing countries also do not deny that the liberalisation of trade in EGs can help address the environment objective to some extent in the short run. However, they also recognise that an unbridled trade liberalisation in EGs could kill their nascent industries that are producers of EGs. There is also risk to other industries where such goods could be diverted. Developing countries are already importing many such goods with low or zero duty, but still such goods produced in developed countries remain expensive for them since they lack the technology to manufacture them. Hence, trade liberalization of EGs can serve only limited purpose. In India the peak applied tariff on industrial goods is 10% and for many EGs the tariffs are still lower, including zero duty. However, developing countries cannot take commitments on bound rates because in their transition phase they may need some tariff protection to give room to the fledgling industry in EGs to at least find its feet. This could see the developing countries emerge as a comparatively cheaper producer of EGs. Further, while the developing countries such as China, India, Malaysia, Thailand, etc. do possess comparative advantage in exports of some EGs, in general, they are already off patent and hence do not command any premium price.

Q9. What is the view of the developing countries regarding raising of the environment regulatory standards?

A9. The developed countries emphasise that the developing

countries need to raise environment regulatory standards since this would give a spur to domestic production in concerned sectors. However, the developing countries hold that without access to ESTs their domestic industry cannot compete with the industry of developed countries. In absence of cheap ESTs, raising of regulatory standards could kill the fledgling industries in developing countries.

Chapter 2

Legal Mandate under International Instruments

Q1. Is there a legal mandate on technology transfer under international instruments?

A1. The issue of TOT is covered in various international instruments, including Agenda 21, the UNFCCC, the Kyoto Protocol, the Bali Action Plan and the WTO's TRIPS Agreement. These international instruments provide that the developed countries undertake technology transfer and provide financial assistance. However, only the WTO Agreement provisions create 'binding' legal obligation. The language used in other instruments can thus at best be interpreted as *soft and non-binding* obligations.

Q2. What are the specific provisions contained in the environment related international instruments regarding TOT?

A2. The following provisions are enumerated below:

(I) AGENDA 21: The Agenda 21 was the blueprint for environmental action adopted by the UN Members at the UN Conference on Environment and Development (Earth Summit), in Rio in 1992. The Agenda refers to the nature of role that governments and international organisations should undertake in promoting and encouraging the private sector to transfer privately owned environmentally sound technologies (ESTs), and states that such role should encompass:

(i) Fiscal or other incentives to facilitate transfer of ESTs by companies;

(ii) Purchase of patents and licences on commercial terms for their transfer to developing countries on non-commercial terms; and

(iii) Provision of financial resources to developing countries to enable them to acquire ESTs.

The Agenda 21 also stresses on ensuring compliance with IPRs, including through equitable and adequate compensation, during the course of acquisition of such technology, including through compulsory licensing. The Agenda also provides for the following:

(i) Promoting long-term collaborative arrangements between enterprises of developed and developing countries for development of ESTs. In this direction it emphasises the need for building a trained human resource pool and infrastructure.

(ii) Joint ventures be promoted, together with FDI, between suppliers and recipients of technologies, taking into account developing countries' policy priorities and objectives. As a part of the same, sound environmental management practices should be transferred and maintained.

The provisions especially enjoin upon the developed countries, as well as other countries in a position to do so, to take the above measures to ensure transfer of ESTs to the developing countries as an integral process to ensure their sustainable development.

The Agenda 21 provides the most emphatic language on TOT of ESTs.

(II) UNFCCC:

(i) **Article 4.1** requires that all Parties, taking into account their common but differentiated responsibilities and their specific development priorities, objectives and circumstances shall ensure:

- Transfer of technologies, and
- Promote and cooperate in the full and prompt exchange of relevant scientific, technological, technical, socio-economic and legal information related to climate change and to the economic and social consequences of various response strategies.

(ii) **Article 4.3** requires developed country Parties included in Annex II of the UNFCCC to provide new and additional financial resources to meet the agreed full costs incurred by developing country Parties in complying with their obligations.

(iii) **Article 4.5** mandates the developed country parties to take all practicable steps to promote, facilitate and finance the transfer or access to ESTs and know-how to other Parties, particularly developing country Parties, to enable them to implement the provisions of UNFCCC. Developed Parties are required to support the development and enhancement of endogenous capacities and technologies of developing country Parties. Other Parties and organisations in a position to do so may also assist in facilitating transfer of such technologies.

(iv) **Article 4.7** emphasises the importance of TOT (along with finance transfer) from developed countries to developing countries before the latter are asked to

take measures to address climate change (**CC**) concerns.

(v) **Article 11.1** defines a mechanism for provision of financial resources on a grant or concessional basis, including for TOT.

Thus, the UNFCCC specifically extends its core principle of '*common but differentiated responsibilities and specific development priorities*' to the aspects of TOT.

(III) Kyoto Protocol, 1997

(i) **Article 3** specifies that funding, insurance and transfer of technology are aspects that need to be considered by developed country parties in implementing their obligations.

(ii) **Article 10** draws a distinction between access to publicly owned technologies and technologies in the public domain, and technologies owned by the private *sector*. With regard to the latter, the Protocol emphasises the need for countries to cooperate in the development of effective modalities for the development, application and diffusion of ESTs. With regard to private sector, the emphasis is on the creation of an enabling environment for the private sector, to promote and enhance the transfer of, and access to, ESTs.

(iii) **Article 11** underscores the need to implement a financial mechanism that would address the need to ensure TOT needed by developing country Parties to meet the agreed full incremental costs of advancing the implementation of their commitments.

(iv) **Article 12** provides for a Clean Development Mechanism (**CDM**), which allows a country with an

emission-reduction or emission-limitation commitment under the Kyoto Protocol (Annex B Party) to implement an emission-reduction project in developing countries. The issue of TOT is not specifically addressed under the provisions on CDM. However, the UNFCCC's modalities and procedures for CDM state that a host country, while considering a project's eligibility as part of CDM, can consider, among other factors, aspects relating to technical features of the project, including how technology will be transferred.

(IV) BALI ACTION PLAN (BAP), 2007

The BAP recognises that enhanced action on technology development and transfer will be critical element in enabling full, effective and sustained implementation of UNFCCC in the post-2012 framework. Accordingly, the BAP emphasises enhanced action on technology development and transfer to support action on mitigation and adaptation, including, *inter alia*, consideration of:

(i) Effective mechanisms and enhanced means for removal of obstacles and provision of financial and other incentives for scaling up the development and transfer of technology to developing country Parties, to promote access to affordable ESTs;

(ii) Ways to accelerate deployment, diffusion and transfer of affordable ESTs;

(iii) Cooperation on R&D of current, new and innovative technology; and

(iv) Effective mechanisms and tools for technology cooperation in specific sectors.

All these obligations emphasise funding as a critical element for enabling TOT. The Agenda 21 directly addresses the issue of IPRs when it emphasises on the need for "purchase of patents and licences on commercial terms for their transfer to developing countries on non-commercial terms as part of development cooperation for sustainable development, taking into account the need to protect IPRs". Other instruments, including the UNFCCC and the Bali Action Plan emphasise on the need for 'removal of obstacles', and the need to promote technology development and transfer, and promoting access to 'affordable' ESTs.

(V) Doha Ministerial Declaration, 2001:

The Para 31(iii) of the Doha Declaration of the WTO provides for negotiations on trade liberalization in context of environment goods and services. The chapeau of Para 31 brings out the need for these negotiations in the context of the mutual supportiveness of trade and environment. Such mutual supportiveness, however, cannot be ensured in absence of transfer of technology.

Q3. What are the provisions on TOT in the WTO's TRIPS Agreement?

A3. The following are key provisions under TRIPS Agreement that refer to TOT:

(i) **Article 7** provides the **objective of the Agreement** and is essentially preambular in nature. It reiterates that protection and enforcement of IPRs should contribute to promotion of technological innovation and to transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge, and in a manner

conducive to promotion of socio-economic welfare and to a balance of rights and obligation under the agreement.

(ii) **Article 8.2** recognises the **principles of the Agreement** and enables the Members to undertake measures that would prevent the abuse of IPRs or resort to practices which unreasonably restrain trade or adversely affect the international TOT.

(iii) **Article 66.2** puts an obligation on part of the developed country members to provide incentives to enterprises and institutions to transfer technologies to LDCs to enable them to create a sound and viable technological base.

(iv) **Article 67** obliges developed country Members to provide, on request and on mutually agreed terms and conditions, technical and financial cooperation to developing and least developed countries.

Chapter 3

Protection of ESTs under the TRIPS Regime

Q1. What sort of IPRs is used to protect ESTs?

A1. Generally, the ESTs are protected through patents. Sometimes trade secret form of protection is used for them.

Q2. What is patent protection?

A2. The TRIPS Agreement obliges Members to make available protection for inventions for at least 20 years, counted from the date of filing of the patent application, when they are new, involve an inventive step and possess industrial application, and are adequately disclosed. This includes inventions, as regards products and processes, in the field of pharmaceuticals, green technologies, other industrial goods, etc.

Once a patent is granted, the owner can prevent others from making, using or selling, importing or offering for sale the patented product/ process. These exclusive rights provide an important incentive for R&D into future inventions to the right holder and are crucial in enabling them to appropriate the investment made. The Governments have given creators these rights as incentive to produce ideas that will benefit society as a whole, especially when the period of protection expires and the inventions enter the public domain.

Q3. What flexibilities to the patent system are provided by the TRIPS Agreement?

A3. The TRIPS Agreement contains the following flexibility to derogate from the normal patent protection system:

(i) Exclusions to patentability pursuant to Article 27.2 and 27.3 TRIPS. Three types of exclusion of inventions from patentability are allowed:

- inventions the prevention of whose commercial exploitation is necessary to protect public order or morality, including
  a. to protect animal or plant life or health or
  b. inventions seriously prejudicial to environment;
- diagnostic, therapeutic and surgical methods for treatment of humans or animals; and
- certain plant and animal inventions.

(ii) Limited exceptions under Article 30, provided that such exceptions do not unreasonably conflict with a normal exploitation of patent and do not unreasonably prejudice legitimate interests of the patent owner. e.g. research exception under which researchers can use patented invention for research purposes, private non-commercial use, prior use i.e. continuing use of invention initiated secretly prior to the priority date/filing date or to allow manufacturers of generic drugs to use the patented invention for purposes of obtaining marketing approval from drug regulatory authorities (Bolar Exception) during the patent protection period so that they could be launched immediately on expiry of patent period.

(iii) **Compulsory licensing** i.e. use without authorization of right holder under Article 31.

(iv) TRIPS Article 40 seeks to guard against **anti-competitive practices** - TRIPS recognizes the right of governments to take measures to prevent patent owners and other holders of IPRs from abusing such rights, unreasonably restraining trade, or hampering the international TOT; and

(v) Parallel imports – If a patent product is sold at cheaper prices in a foreign country by the patent holder or a Party licensed by the patent holder, and if the product is imported, then it is called parallel import. Under Article 6 of TRIPS, a WTO Member is free to decide whether to allow parallel imports or not. Hence products sold at a lower price elsewhere in the world by or with the permission of the right holder can subsequently be imported without the approval of the patent owner.

Q4. What is compulsory licensing (CL)?

A4. The TRIPS Agreement does not use the term "compulsory license" but rather uses the term "**use without authorization of the right holder**". Article 31 TRIPS covers CL granted to third parties for their own use and CL granted for use by or on behalf of Governments without the authorization of the right holder. A CL can be said to be a licence given by a government authority to a person other than the patent owner which authorizes the production, importation, sale or use of the patent-protected product or use the patented process without the consent of the patent owner.

Q5. Under what conditions is a compulsory license granted?

A5. CL, including government use without the authorization of the right holder, is **allowed without limitation as to grounds** but subject to conditions **aimed at protecting the legitimate interests of the right holder**. The **key conditions** for the grant of CL in line with Article 31 are:

(i) To make at least an unsuccessful attempt to acquire a voluntary licence from the right holder on reasonable terms and conditions within a reasonable period of time;

(ii) To pay adequate remuneration in the circumstances of each case, taking into account the economic value of the licence;

(iii) Use is to be predominantly for the supply of the domestic market of the Member country granting the CL; and

(iv) To subject to judicial / other independent review by a distinct higher authority, the legal validity of any decision as regards CL.

Further, the **scope and duration** of CL is to be limited to purposes for which it was granted. CLs should be liable to termination when the circumstances that justified their creation no longer apply.

Q6. What are some examples of the cases where the countries allow for invoking of the compulsory licensing provisions?

A6. The IP laws of countries generally provide for CL on the following grounds:

(i) Non-working of the patent by the patent holder in the country.

(ii) In the event that public interest is impacted.

(iii) National emergency.

Q7. Under what circumstances the conditions governing compulsory licensing may be relaxed?

A7. As per Article 31 TRIPS, the WTO Members may relax some of the above conditions under the following circumstances:

(i) Attempt to obtain a voluntary licence need not be made in cases of national emergency or other circumstances of extreme urgency, in cases of public non-commercial use, or when a CL is granted as a remedy in adjudicated cases of anti-competitive practices; and

(ii) Condition to use CL predominantly for supply to the domestic market may be relaxed when the Government grants a CL to remedy in adjudicated cases of anti-competitive practices.

Q8. What is trade secret type of protection?

A8. A trade secret is a formula, practice, process, design, instrument, pattern, or compilation of information which is not generally known or reasonably ascertainable by proper means by other persons, by which a business can obtain an economic advantage over competitors or customers. The owner has to take reasonable efforts to preserve the secrecy. A big disadvantage is that there is no legal limitation to decipher the secret, say through, reverse engineering. The only protection that a trade secret provides is that the information cannot be acquired through dishonest means.

Q9 What is trade secret (TS) protection regime under TRIPS?

A9. Under Art 39.2 of TRIPS, the WTO Members must provide an opportunity to prevent undisclosed information (**UI**) from being disclosed to, acquired by, or used by others without the consent of the owner in a manner contrary to honest commercial practices. The protection is required to be provided under the following circumstances:

(i) When the information is secret in sense that it is not generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question, and is not generally known to public;

(ii) Information as a whole may be secret, such as formula for Coca-Cola, or the information is composed of individual pieces of information that may be in public domain, but the compilation of which is not, such as a law firm's client chart;

(iii) Has commercial value because it is secret and the value would be lost or impaired if information ceased to be secret, such as the formula of Coca-Cola would be of less value to Coca-Cola Company if all competitors also had access to it; and

(iv) UI has been subject to reasonable steps, depending on nature and value of the information to be protected, by persons lawfully in control of information, to keep it secret.

Chapter 4

Doha Declaration on Public Health

Q1. What was Doha Declaration on Public Health?

A1. The Doha Declaration on the TRIPS Agreement and Public Health as adopted on 14 November 2001 responded to concerns about the possible implications of the TRIPS Agreement for public health problems afflicting many developing and least-developed countries, in particular access to patented medicines. The key provisions of the Declaration were:

(i) TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.

(ii) Members have right to use, to full, the provisions of the TRIPS Agreement that provide flexibility for this purpose.

(iii) TRIPS Agreement should be interpreted and implemented in a way that supports Members' right to protect public health and, in particular, to promote access to medicines for all.

(iv) Highlighted the importance of objectives and principles of the TRIPS Agreement regarding the interpretation of its provisions.

(v) While maintaining commitment to the TRIPS Agreement, the Declaration recognised the following flexibilities in the Agreement:

- Each Member has right to grant compulsory license (**CL**) and freedom to determine the grounds upon which such licences are granted;
- Each member has right to determine what constitutes national emergency or other circumstances of extreme urgency, such as that arising from public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics; and
- Each Member is free to establish its own exhaustion regime without challenge - subject to the general TRIPS provisions that prohibit discrimination on the basis of nationality of persons (National Treatment and Most Favoured Nation principles of the WTO).

While emphasizing the flexibility in the TRIPS Agreement to take measures to promote access to medicines, the Declaration recognised the importance of IPRs for developing new medicines and reaffirmed the commitments of Members in the TRIPS Agreement. Besides, the above clarifications, the Declaration (Para 6) also sought to amend the TRIPS Agreement (please refer to the response to Q5 below).

Q2. What are the exhaustion provisions in the TRIPS Agreement? What is significance of the exhaustion regime?

A2. Under Article 6 of the TRIPS Agreement, the WTO Members can choose between national or international exhaustion, and, if part of a regional free trade area, regional exhaustion. Under national exhaustion, a right holder can use his IPRs to prevent importation of protected products from other countries even if they have been put

on the market there by him or with his consent. Under international exhaustion, the right holder is not able to do this since his IPRs are held to have been exhausted by his earlier marketing of the product.

An international exhaustion regime facilitates **parallel importation** of the same product sold at lower prices in other countries. This allows the developing country Members to, say buy medicines from cheaper sources. The national exhaustion encourages market segmentation and allows maintenance of differential pricing, taking into account the level of development in each country.

Q3. What led to the decision under Para 6 of the Doha Declaration?

A3. Para 6 of the Doha Declaration recognised the problem of countries with insufficient or no manufacturing capacities in the pharma sector in making effective use of CL to deal with public health problems when they need to buy from generic producers in third countries where the medicines needed are patent protected. Accordingly, it instructed the TRIPS Council to find an expeditious solution to the problem.

Countries with insufficient or no manufacturing capacities in the pharmaceutical sector cannot issue a CL for domestic manufacturing and can only import under a CL. This, in itself, is possible under Article 31 TRIPS as Members can issue CLs for importation as well as for domestic production. However, the potential problem was whether supply from generic producers in third countries would be available in cases where the needed medicine was patent-protected in exporting country. The question arose because the TRIPS Agreement limits the amount countries can export under a CL - Article 31(f) TRIPS requires that the

production under a CL be "predominantly for the supply of the domestic market". This constraint was expected to become more important as some developing countries with generic industries and export capacities, such as India, were coming under an obligation to provide product patent regime for pharmaceutical products from 2005 (following an end to the transition arrangements under Article 65.4 TRIPS).

Q4. What was the decision on the implementation of Paragraph 6 of the Doha Declaration?

A4. Following the instruction given by the Doha Declaration to seek an expeditious solution to the problem outlined in A3 above, the Members adopted a General Council Decision on the implementation of Paragraph 6 of the Doha Declaration on 30 August 2003 (WT/L/540). This waives the following obligations of Article 31 TRIPS under certain circumstances:

(i) Obligation of exporting Member under Article 31(f) TRIPS does not apply to the extent necessary to enable that Member to authorize production and export of needed pharmaceutical products under a CL to those countries that do not have sufficient capacity to manufacture them. This derogation is subject to certain conditions to ensure transparency in operation of the system and ensure that only countries with insufficient domestic capacity import under it. It also provides for safeguards against the diversion of products to markets for which they are not intended; and

(ii) Requirement under Article 31(h) to pay adequate remuneration for CLs is modified to avoid double remuneration of the right holder. If a CL has to be granted in both the exporting and the importing

countries, remuneration need only be paid in the exporting country.

The waiver provisions of the 2003 Decision came immediately into effect on 30 August 2003 and would remain applicable until the date on which the TRIPS amendment takes effect for a Member. Another General Council Decision of 6 December 2005 transformed the waivers contained in the 2003 Decision into a permanent amendment to the TRIPS Agreement through insertion of a new Article 31*bis* TRIPS that comprised of main additional flexibilities allowed by 2003 Decision, and a clarification that existing TRIPS flexibilities are preserved. It also provided for:

- an Annex setting out the terms and conditions for use of additional flexibilities; and
- an Appendix to the Annex dealing with the assessment of manufacturing capacities.

The amendment will be incorporated into the TRIPS Agreement when two-thirds of the Membership has ratified the amendments. There was a deadline of 1 December 2007 set for this, but the General Council extended the deadline to 31 December 2009 and subsequently to 31 December 2011. Given that the content of the August 2003 Decision and the proposed amendment of the TRIPS Agreement is the same, the substance of the legal regime applying to Members will remain the same, whether they have accepted the Protocol or not.

Q5. What is the scope of the Para 6 decision?

A5. The system covers any patented products or products manufactured through a patented process, relating to the

pharmaceutical product and needed to address public health problems. The eligible importing Members are:

- LDCs - they are automatically recognised as eligible to import under the system; and
- Any other Member that notifies the TRIPS Council of its intention to use the system. This is a one-time notification that can be made by a Member at any time.

No restriction applies to the eligibility of Members as exporting countries. However, as in the case of CL in general, the additional flexibility under the Para 6 System is an option, not mandatory, and therefore no Member is obliged to implement the system in its domestic legislation. However, the Preamble of the 2003 and 2005 Decisions underlines that a rapid response should be given to importing Members seeking to obtain supplies under the system.

Q6. When would the need for using the Paragraph 6 system not arise?

A6. There is no need to use Para 6 system when:

(i) an agreement can be reached with the originator company to supply medicines at affordable prices or to grant a voluntary licence to a generic producer;

(ii) the product can be manufactured locally;

(iii) the product can be obtained from a generic source in a non-Member;

(iv) the product is not patent-protected in the exporting Member; or

(v) only the non-predominant share of the production is exported by generic manufacturer.

Q7. Did the Doha Declaration on Public Health harbinger the compulsory licensing regime under TRIPS? If not, what was its significance?

A7. The flexibility to issue CL always existed in the TRIPS Agreement, ever since it took effect in January 1995. A CL could be issued under Article 31 of the original TRIPS Agreement and not necessarily under the 2003 decision. The 2003 decision or the **"Paragraph 6" decision** only deals with CLs to produce for export. Issuing CLs for supplying to the domestic markets was a flexibility always available under TRIPS. However, the Declaration was important for clarifying the flexibilities under TRIPS Agreement and assuring governments that they can use the flexibilities, because some governments were unsure about how the flexibilities would be interpreted.

Q8. How have the WTO Members responded to the Paragraph 6 system?

A8. All WTO member countries are eligible to import under this Decision. However, 23 developed countries are listed in the Decision as announcing that they will **not use the system to import**. They are Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and the US. Since they joined the EU, the list now includes 10 more: Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia.

11 other members announced voluntarily that they would **only use the system as importers** in situations of national emergency or other circumstances of extreme urgency. They are - Hong Kong China, Israel, Korea, Kuwait, Macao

China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and United Arab Emirates.

The WTO waiver on its own is not enough to invoke the system. To use the system, potential exporting countries have to change their domestic patent laws, since earlier their Patent law allowed CL to be used predominantly for the domestic market in compliance with the original TRIPS provision (Article 31). Once two-thirds of members have formally accepted it, the amendment will take effect in those Members and will replace the 2003 waiver for them. For each of the remaining Members the waiver will continue to apply until that Member accepts the amendment and it takes effect. So far only Norway, Canada, India and the EU have formally informed the TRIPS Council that they have done so. India's Patent laws have been suitably amended to invoke the usage of this flexibility. 28 Members, including US, EU, Canada, Australia, Switzerland, Korea, Norway, Japan, China, Egypt, Mexico, Brazil, Zambia, Pakistan and India have given their intimation to the TRIPS council of accepting the 2005 Protocol.

Q9. Are there examples of cases where Compulsory Licence has been used? What has been the experience?

A9. The cases for use of CL are listed below:

(i) For manufacturing several life saving drugs, CL has been used by some countries at domestic level. A case in point is Thailand for anti retrovirals.

(ii) Rwanda, a LDC, was the first country to make use of the new CL provisions that are proposed to form Article 31bis of TRIPS. Canadian company Apotex Inc. was awarded a CL export licence under the

provisions to supply a combination AIDS drug to satisfy Rwanda's health needs. This is the only case where the CL has been granted under the Article 31bis provisions. Invoking of CL came for strong criticism from Apotex.

(iii) Zambia granted a CL to a Zambian national company on 21 September 2004 for a triple combination AIDS therapy containing lamivudine, stavudine and nevirapine. The CL was to last until the state of emergency, which was declared on 3 September 2004, was over. The royalty to be paid to the patentees was 2.5 per cent.

(iv) Indonesia granted a CL to its Government on 5 October 2004 in respect of nevirapine and lamivudine. The royalty to be paid to the patentees was 0.5 per cent.

(v) On 29 November 2006, Thailand issued a CL, also for an HIV/AIDS drug owing to the fact that it had insufficient capacity to manufacture such drugs. The government issued the CL to import Merck's drug efavirenz from India to supply 200,000 people a year for five years (until 2011). Merck will receive 0.5 per cent of the total sale value of the generic product. There has been criticism of Thailand for not negotiating with the patentee prior to granting the CL. However, Thailand stressed that it is seeking to address a public health emergency and the material imported will be used for a non-commercial public treatment programme. In these circumstances, there is no obligation to negotiate with the patentee under Article 31(b).

(vi) Brazil also awarded a CL to import efavirenz from India on 4 May 2007. Brazil initially used the threat to invoke CL and when that failed to check prices it had

to issue CL. It undertook two years of negotiations with the patentee, Merck before issuing CL.

In both (v) and (vi) above, there was no need to use the provisions under Article 31bis because there is no patent protection for efavirennz in India, and hence no CL for export was necessary.

(vii) On 14 April 2010, Ecuador issued CL for Ritonavir, an antiretroviral drug to combat HIV/AIDS to a local company, Eske Group, which is the local distributor of Indian company Cipla.

There have been at least five CLs granted under TRIPS in the past three years. The majority of CLs have been granted for domestic manufacture and use only. Hence, they rely on a supply from home-grown manufacturers or from non-patented countries.

Despite Para 6 system being used just once in 7 years since 2003, the patentees perceive that the threat is real, and an increased willingness of the Governments to grant CLs provokes them into greater discounts.

Q10. Why has Para 6 system been in news recently?

A10. In an informal session of the TRIPS Council held on 12 Feb 2010, the Members, especially from the developing countries brought out that the Para 6 System that was expected to genuinely and completely address public health problems faced by countries with insufficient or no manufacturing capacities in the pharmaceutical sector, had failed to achieve its objectives. The developing countries expressed disappointment that the system has been used only once in the Canada-Rwanda case in 7 years since 2003. Moreover, this lone case took 3 years for the process to be completed! What was supposed to be an

expeditious solution to the crisis in access to medicines has not worked. There was a perception that the procedures for invoking the system are quite cumbersome to comply with and this has made the use of system complicated. The developing countries pointed out that the Para 6 was meant to address public health problems in emergency situations, and therefore, time frame should be a priority. Accordingly in the informal session of the TRIPS Council, the developing country Members felt that there was a need to brainstorm the issue in a workshop to assess how the operationalisation of the system could be made more effective. However, other countries including Canada, Switzerland, the US and the EU felt that there was nothing wrong *per se* with the system established under the Para 6.

Some of the Members also expressed concern at the slow pace of acceptance of the Protocol for amendment of TRIPS Agreement.

Chapter 5

How can Transfer of Technology in Environmentally Sound Technologies be Encouraged?

The mechanisms suggested in this Chapter build on the legal provisions in context of TOT that exist in the Agenda 21, UNFCCC, Kyoto Protocol, the Bali Action Plan and Para 31 of the Doha Ministerial Declaration, 2001. Reliance is also placed on the Doha Declaration on Public Health.

Q1. What are the implications of the TRIPS Agreement on TOT relating to ESTs?

A1. The IPR protection regime under TRIPS tempts IPR holders to charge exorbitant and commercially unviable prices for transfer or dissemination of technology, which is protected through such IPRs. The IPR holders in a bid to retain competitive edge (fear of loss to low cost production in developing countries) refuse technology transfer or prescribe restrictive licensing with such transfer in form of geographical restrictions or limited period of licensing. Despite Article 66.2 TRIPS, there has not been any meaningful TOT in favour of LDCs. Moreover, even if there was any intent to facilitate technology transfer, the minimum level of commitment as regards IP rights would prevent WTO Members from relaxing their IPR regimes to allow for liberal access to TOT.

Hence, there may be a need to re-interpret/ introduce flexibilities in TRIPS Agreement to harmonise the private IP rights with environment objectives to ensure that the developing countries are able to pursue the path of sustainable development.

Q2. How could TOT in context of ESTs be encouraged?

A2. The developing countries such as India, want an urgent and comprehensive action to promote TOT to address the critical global climate change concerns. India views that the developed world has to accept some minimum relaxation of IP regime owing to the historical responsibility for the current climate situation. **However, given the fact that the TRIPS Agreement sets certain minimum standards in respect to the IP regime that the WTO Members are allowed to have, there can be no relaxation of the IP regime to facilitate TOT in context of the ESTs unless the WTO Members decide to relax the TRIPS provisions.** In this regard, some of the flexibilities that could be sought to provide an access to cutting edge ESTs at fair and reasonable costs to the developing countries are:

(a) Political reaffirmation of the right of the WTO Members to use all the existing flexibilities in the TRIPS Agreement - exemptions to patentability, exceptions to patent rights, and compulsory licensing, etc. - to access ESTs. Such reaffirmation was made in the Doha Declaration on Public Health in context of access to patented medicines.

(b) WTO Members may also agree that they shall exercise due restraint in launching dispute settlement proceedings under the WTO against the developing country Members for alleged violations of the TRIPS provisions arising from actions taken to access relevant ESTs. The 'due restraint' provision existed in the WTO's Agreement on Agriculture in the context of subsidies extended by the WTO Members, essentially the developed countries, for agriculture activities.

(c) Accept compulsory licensing on lines of that agreed in the WTO Doha Declaration on TRIPS and Public Health under the Para 6 mechanism for export of technology to enterprises in countries with insufficient or no manufacturing facilities for that EST.

(d) All publicly funded (where Government contribution is 50% or more of the total investment) ESTs under patent protection in developed counties should be transferred to enterprises of developing countries free, without any licensing fee or royalty payment.

(e) Relaxations of IP protection (such as reduction of the patent period from the minimum stipulated 20 years), in cases where the Multilateral Environment Agreements (**MEAs**) contain obligations to phase out certain substances/ technologies and replace them with specified ESTs, and on EGs on which the developed countries seek tariff liberalisation in the WTO.

An advantage of going through the TRIPS route would be that it alone is capable of creating legally binding commitments.

The UNFCCC 'common but differentiated responsibility' principle would have to be respected in the context of TOT too. These measures would ensure that the owners of ESTs sell/ transfer such technologies and products at fair and favourable terms and conditions upon demand to interested developing countries for the purposes of tackling environmental challenges. The developing countries would then be able to address their felt needs with the most appropriate, and cost effective ESTs, and through manipulating the technology to suit their local needs, if need be.

Q3. Is a CL regime for access to ESTs similar to the CL regime as exists for the pharmaceutical sector justified?

A3. As discussed in Chapter 3, compulsory license is justified when there is an important public interest to be addressed, such as public health interests, addressing CC concerns, etc. Thus there is a justified claim to use CL for access to ESTs.

However, a regime to access ESTs exactly similar to that for pharma sector may not deliver the desired results. The provisions of Article 31 of the TRIPS Agreement to provide for CL for sales within the domestic market are extremely cumbersome to comply. The grant of CL on grounds of encouraging transfer of ESTs is TRIPS-compatible, as Article 31 TRIPS does not restrict the grounds on which CL may be granted. However, some TRIPS provisions, in particular Article 31(b) regarding efforts to obtain prior permission; Article 31(g) regarding termination of such licence; Article 31(h) regarding taking into account the economic value of the licence; and Article 31(l) regarding strict conditions for dependent patents, may prove to be hurdles in the quick and effective transfer of such ESTs where environmental standards and measures need to be complied with within fixed time limits. In view of this, the TRIPS Council may need to examine whether Article 31 of TRIPS Agreement can be applied effectively to deal with contingencies that CC poses.

Similarly, the procedure under Para 6 system for issuing CL to export to countries that do not have sufficient manufacturing capacity is quite cumbersome and has been used only once by Canada to export Apotex drug to Rwanda. This procedure may again need to be liberalised to allow its effective use to deal with CC contingencies.

Q4. Can there be a non-IP route to encourage TOT in ESTs?

A4. The following could be some of the ways, which could be explored in this direction:

(i) Developed countries may create a global patent pool through purchase of privately held ESTs in all sectors, for transfer to developing countries on non-commercial terms.

(ii) Providing financial resources/ loans to the developing countries to enable acquisition of ESTs.

(iii) Developed countries may also provide fiscal incentives, such as tax breaks, or other incentives to their private entities to transfer technology to enterprises in developing countries.

(iv) Focus may be placed on establishing frameworks for mutually beneficial joint venture economic arrangements, including joint R&D activities, between developed and developing country enterprises to stimulate innovation and sharing of resulting IPRs. Such joint ventures may especially keep in view the developing countries' policies and priorities.

(v) Developed countries could commit to devote a part of their R&D activities to the special needs of developing countries.

(vi) Help the developing countries build requisite infrastructure/ capacity.

(vii) Providing training to officials from developing countries and establish channels for exchanging information.

(viii) Developed countries may put in place codes of conduct to ensure that private players do not deny access to proprietary ESTs and provide such access on reasonable terms. The threat of compulsory licensing could be used in this regard.

(ix) Political reaffirmation of the freedom to the countries to regulate entry and operation of foreign investors to ensure that they bring the latest ESTs as part of FDI inflows.

(x) Creating monitoring mechanisms and performance indicators in respect of monitoring and evaluating the effectiveness of implementation of a TOT framework.

A suitable regulatory environment in the recipient countries could also aid TOT. However, this issue falls under the domestic policy ambit of recipient countries.

Q5. How can a funding mechanism help transfer of technology?

A5. Even when some environmental goods and technology can be cost saving in the long run due to saving in energy and other materials, often developing countries are not able to adopt such technologies due to their high initial cost and also the cost associated with re-training/ maintenance, etc. Hence, there is a need to provide financial assistance to developing countries to aid the process of technology transfer and meeting other costs involved in the process of addressing environment concerns.

A '**Green Technology Fund**', which provides a source for predictable, sustained and adequate funding could be set up for the purpose. The funding mechanism is essentially a **non-IP route** to transfer technology. The Members from developed countries could contribute some fraction, say 0.1%, of their GDP to this fund. The other Members could

also freely contribute as per their respective capabilities. Further, tax/ other levies on international aviation and maritime fuels and/ or carbon tax on fossil fuels could be used to add to this corpus. This funding should be over and above all existing and likely flows, including that from CDM and other carbon market proceeds, from both domestic and foreign official and private sources. The UNFCCC meeting in Copenhagen in Dec'09 also explored the possibility of creating a '**Green Climate Fund'** for addressing CC adaptation and mitigation measures. A part of this could be earmarked for TOT purposes.

The fund could be used for some of the following purposes:

(i) Creating a pool of ESTs that can be used by developing countries without any licensing fees or royalties.

(ii) Providing grants to developing countries that intend to import a specific EST.

(iii) Providing soft loan to countries for addressing other green concerns.

(iv) Meeting cost of conversion of existing manufacturing facilities or of establishing new facilities.

(v) Meeting cost of R&D activities, including joint R&D and demonstration.

(vi) Aiding technology adaptation and capacity building requirement for the same.

(vii) Meeting cost of retraining and dissemination of know-how.

(viii) Meeting operational costs.

(ix) Meeting cost of monitoring and verification.

However, a fund of $100 billion as contribution of the developed countries by 2020 as was discussed at Copenhagen would be woefully inadequate to even meet the adaptation and mitigation needs of developing countries, including LDCs. This cannot meet the funds required for TOT.

Useful Web Links

- www.commerce.nic.in
- www.wto.org
- www.unctad.org
- www.worldbank.org
- www.wipo.int
- www.fao.org
- www.unescap.org
- www.artnetontrade.org
- www.ictsd.org

Other Publications of the Centre for WTO Studies

- FAQ on WTO Negotiations in Agriculture
- FAQ on WTO Negotiations in Non Agriculture Market Access (NAMA)
- FAQ on WTO Negotiations in Services
- FAQ on Geographical Indications
- FAQ on WTO Agreement on Subsidies and Countervailing Measures
- FAQ on WTO Agreement on Safeguards
- FAQ on WTO Compatibility of Border Trade Measures for Environmental Protection
- Review of Trade Policies of India's Major Trading Partners
- ***Discussion Paper 1:*** India's Duty Free Tariff Preference Scheme: Case Study for Select LDCs
- ***Discussion Paper 2:*** Cotton Production, Exports and Price: A Comparative Analysis of India and USA
- ***Discussion Paper 3:*** Study on Identification of Select Textile and Wool and Woollen Products Having Export Potential to Chile, Colombia and Peru
- ***Discussion Paper 4:*** Trade Facilitation in WTO and Beyond
- Bimonthly newsmagazine titled 'India, WTO and Trade Issues'

All the above publications are available on the website of the Centre for WTO Studies, ***http://wtocentre.iift.ac.in***

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The Centre for WTO Studies has been functioning since November 2002 at the Indian Institute of Foreign Trade. The major objective of the Centre is to provide research and analytical support to the Department of Commerce on identified issues relating to the World Trade Organisation.

The Centre has recently undergone considerable strengthening. It has now a wider mandate and is tasked to carryout research activities, bring out newsletters on WTO related subjects, organise outreach and capacity building programmes through seminars, workshops, subject-specific meetings etc. and to be a repository of important WTO documents in its Trade Resource Centre. A Steering Committee has been constituted to guide the work of the Centre.

The Centre is currently engaged in research activities on following WTO related subjects:

- Agriculture
- Intellectual Property Rights
- Agreement on Sanitary and Phytosanitary Measures
- Agreement on Technical Barriers to Trade
- Trade Facilitation
- Technology Transfer
- Issues relating to Environment and Trade
- Subsidies including Fishery Subsidies

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