TRIPS Agreement and 10th WTO Ministerial

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Introduction

The Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS) sets minimum standard for the protection and enforcement of intellectual property rights. However, TRIPS was not the end but the beginning of *ratcheting up* of IPR protection and enforcement standards. Developed countries have enhanced the protection and enforcement of IPR known as TRIPS plus provisions through various free trade agreements (FTA), bilateral investment treaties (BIT) and technical assistance during the last 20 years. Even though many developing countries have undertaken TRIPS Plus standards majority of developing countries are outside the TRIPS plus obligations. Therefore, it is important to prevent any further enhancement of IP standards at the multilateral level and bilateral level.

However, the last 20 years have provided an opportunity to assess the implications of enhanced IP protection enforcement standards on the socio-economic development. In other words these 20 years provide an opportunity to WTO Member States especially for the developing country Member States to reflect whether TRIPS facilitates the development needs of developing countries. The upcoming Nairobi Ministerial Conference of WTO thus offers an opportunity to: First to the work program on TRIPS as set in the Doha Ministerial Declaration (Doha Declaration). Second, it also offers an opportunity to revisit the provisions of TRIPS to meet the social and economic development needs of developing countries.

First part discusses the experiences of last 20 years of TRIPS and its implications for socio-economic development needs especially in the context of developing countries. Second part explains the existing work program on TRIPS Program as set out in the Doha Declaration the inbuilt review process of the TRIPS Agreement. Third part deals with two impending decisions to be taken at the Nairobi Ministerial Conference. Fifth part deals with the recommendations.

Impact of TRIPS on Access to Medicine

TRIPS, primarily an agenda of the pharmaceutical industry, found place in the Final Act of Uruguay Round, which established the WTO Agreements. It not only imposed compulsory product patent protection, but also extended the period of patent protection to 20 years.1 Further, it also imposed mandatory patent protection for microorganisms. Apart from the access to medicine context, the international IP regime, especially the patent regime, sets monopoly prices on technology transfer and disrupts the technology catching up strategy for industrial development.2 During the last 20 years, the TRIPS Agreement represents one of the classic cases of corporate capture of international trade agenda and also a new chapter of struggle for access to medicines.3

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3 The Final Act of Uruguay Round was signed in April 1994 at Marrakesh and it came into force on 1 January 1995.
In the context of medicines TRIPS removes the policy space with regard to patenting of pharmaceutical inventions and put a minimum level of protection and enforcement of IP rights, which include the compulsory product patent protection, on WTO Members. They remove the competition in the medical products, especially in medicines, by eliminating the possibilities of generic production, resulting in high prices for many life-saving medicines. Further, they eliminate the possibilities of generic competition on new medicines, often protected with patents in the absence of compulsory licence (CL) and government use.

**TRIPS Patent Regime and Access to Medicines**

During the first five years of the TRIPS Agreement itself, patent monopoly resulted in the death of thousands of people in the developing world, who could not access the Antiretroviral (ARV) medicines despite its availability. This was due to the exorbitant price of medicines. Popular mobilisation and the non-availability of product patent protection in India in the late 1990s resulted in the production of affordable generic versions of ARVs and subsequent scaling up of ARV treatment for people living with HIV/AIDS.4

Patent monopoly legitimises the high prices for new medicine and denies access to medicine. For instance, Gilead Sciences charges USD 84,000 for 12 weeks of treatment for Hepatitis C with its newly approved Sofosbuvir. Sofosbuvir is a new class of medicine for Hepatitis treatment known as direct-acting antiviral (DAA). The DAA is expected to revolutionise the Hepatitis C treatment by replacing the existing pegylated interferon-based treatment regime.

Apart from communicable diseases, a larger crisis is unfolding in developing countries with regard to access to treatment to Non Communicable Diseases (NCD). According to IMS topline data, oncology accounts for the largest market share among top 20 global therapy areas with a sales turnover of USD 67.13 billion followed by pain (USD 57.25 billion) and anti-diabetics (USD 54.37 billion), respectively.5 In developing countries, cancer itself claims more lives than those due to AIDS, Malaria and TB together.6 Approximately, 65 per cent of deaths due to cancer occur in low and middle-income countries. Out of the 14 million people diagnosed with cancer in 2012, 57 per cent belong to these countries. The Economist states that the cancer situation in developing world is worse than AIDS.7 The high prices of cancer medicine make these medicines unaffordable not only in developing world, but also in the developed countries.8

Patent fails not only in ensuring access to medicines at affordable price, but also in stimulating R&D. Pharmaceutical MNCs justify patent monopoly always as a tool for stimulating R&D investment by extending a statutory monopoly to the patented invention. Even though there are many new medicines introduced for the treatment of cancer, especially for the targeted therapy, the efficacy of these medicines compared to the existing ones is questionable.

The patent system also failed to meet the R&D needs of developing countries. According to a study by the Drugs for Neglected Disease Initiative (DNDi), out of 336 new chemical entities (NCEs) introduced from 2000 to 2011 only 4 NCEs were approved for neglected diseases.9

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4 Unlike many developing countries, India used the 10 years’ transition period available under the TRIPS Agreement and introduced product patent protection to pharmaceutical inventions only in 2005.
7 Ibid
same study also found that out of 148,445 clinical trials registered in December 2011 only 2016 were for neglected diseases. This clearly shows that patent monopoly cannot attract R&D investment in those disease areas, which are predominantly affecting developing country population, who cannot buy products at an exorbitant price. Further, there is no increase in the R&D investment of pharmaceutical industry in developing countries. Recently, AstraZeneca closed down its R&D facility on TB in India.\(^{10}\) This clearly exposes the pro-IP propaganda such as increased Foreign Direct Investment (FDI) and R&D investment in developing countries as a result of TRIPS compliance.\(^{11}\)

Pharmaceutical MNCs developing original medicines (originator companies) did not bring any FDI in countries like India to establish new manufacturing facilities. However, FDI is used to acquire generic companies in order to use their marketing and distribution network to access the Indian market. The Parliamentary Standing Committee on Commerce recommended ban on the Brownfield FDI in pharmaceutical sector citing that MNCs control on generic companies would neutralise the possibility of use of TRIPS flexibilities.\(^{12}\)

Contrary to the propaganda, patent is functioning as a tool for protecting monopoly to contain competition rather than for the stimulation of R&D. A group of academics observes “the role of patents in corporate management has undergone a change from a defensive means to protect research and development outcomes to become strategic assets to influence the conditions of competition.”\(^{13}\)

The failure of patent to stimulate R&D resulted in the call for fresh look at the role of patent and public policy. Two economists argue that “...public policy should aim to decrease patent monopolies gradually but surely, and ultimate goal should be the abolition of patents”.\(^{14}\) Another academic notes that “Even pharmaceutical and biotech companies usually do not need more than about a decade of monopoly power to encourage their very large investments in new drugs.”\(^{15}\) There is an urgent need to interrogate the international IP regime in general and patent protection for pharmaceuticals in particular, which does not reflect the health and development needs of people, especially those living in developing countries.

Recently Economist magazine stated, “Today's patent regime operates in the name of progress. Instead, it sets innovation back. Time to fix it”.

The Agreement not only established patent monopoly and thus eliminated generic competition and lower prices for new medicines, but also failed to bring investment in R&D in developing countries. Moreover, there are legal, institutional and political bottlenecks, which prevent the effective use of TRIPS flexibilities. This situation has prompted the UNDP-appointed Global Commission on HIV and the Law to observe that “TRIPS has failed to encourage and reward the kind of innovation that makes more effective pharmaceutical products available to the poor, including for neglected diseases. Countries must therefore develop, agree and invest in new systems that genuinely serve this purpose, prioritising the most promising approaches

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including a new pharmaceutical R&D treaty and the promotion of open source discovery”. Further, the Commission recommended “The UN Secretary-General must convene a neutral, high-level body to review and assess proposals and recommend a new intellectual property regime for pharmaceutical products. ...Pending this review, the WTO Members must suspend TRIPS as it relates to essential pharmaceutical products for low- and middle-income countries”. Developing countries like India along with like-minded countries should submit proposals to amend the TRIPS regime to address the Socio-Economic development needs such as removal of the compulsory product patent protection or shortened duration of patent etc. The Parliamentary Standing Committee on Commerce recommended to the government “the Government must take up the TRIPS agreement afresh at an appropriate forum and collectively work with world governments to ensure that flexibility in periodicity of exclusive manufacturing right to a patentee company is introduced in the patent regime depending upon the amount of expenditure incurred by the patentee as well as the extent of its contribution in the R&D”. This is perfectly fit within Section 71.1 inbuilt review of the TRIPS Agreement and the Doha Declaration states “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”. Therefore the proposal to amend the TRIPS Agreement is well within the exiting mandate.

**TRIPS and Doha Development Agenda**

The Doha Declaration contains two references to the work programmes on IPRs. First in Para 12 dealing with the implementation issues related to various WTO agreements including the TRIPS Agreement.

The TRIPS Agreement itself contains the following three inbuilt review of its provisions.

First, the review of Article 27.3 (b) dealing with the patent protection of micro-organisms. According to this article the “provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement”. Article 27.3 (b) came into force in 1995. The review was initiated in 1999 and till date three is no outcome.

Second, Article 71.1 of the TRIPS Agreement provides mandatory review of the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. Hence this review is to be initiated 2010. According to Art.71.1 “ The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments, which might warrant modification or amendment of this Agreement. (Article 71).

Third, the Council for TRIPS shall keep under review the application of the provisions of this Section; the first such review shall take place within two years of the entry into force of the WTO Agreement. Any matter affecting the compliance with the obligations under these provisions may be drawn to the attention of the Council, which, at the request of a Member, shall consult with any Member or Members in respect of such matter in respect of which it has not been possible to find a satisfactory solution through bilateral or plurilateral consultations between the Members concerned. (Art. 24.2)

Second, Para 17 to 19 provides specific mandate to work programme on TRIPS. Para 1& refers to the Doha Declaration on the TRIPS Agreement and Public Health. This Declaration asked the Member States to find a solution to issue compulsory license for export purpose to meet the

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public health needs of countries without manufacturing capacity in the pharmaceutical sector. Second, it also provided waiver for least developing countries with regard to the product patent protection of pharmaceutical inventions. Para 18 provides negotiating mandate for the establishment of a multilateral register on “multilateral system of notification and registration of geographical indications for wines and spirits by the Fifth Session of the Ministerial Conference”. Further, the same Para also states that “the extension of the protection of geographical indications provided for in Article 23 to products other than wines and spirits will be addressed in the Council for TRIPS pursuant to paragraph 12 of this Declaration” i.e. as an implementation issue.

Para 19 while recognising the inbuilt review in the TRIPS Agreement also provided mandate 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”.

Therefore the important three issues falls under the Doha Work programme are Patent Protection of microorganisms, relation with TRIPS and CBD and the extension of geographical indications.

**TRIPS and Convention on Bio Diversity (CBD)**

CBD was concluded in 1992 and ratified by more than 180 countries, which has three main objectives, viz. conservation of biological diversity, the sustainable use of biological resources and fair and equitable benefit sharing. Article 8 (j) of the CBD recognises knowledge, innovation and practices and creates an obligation to encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices. Thus CBD recognises that benefits of scientific research should be shared with indigenous and local communities when such research are based on such knowledge. To prevent the misappropriation of genetic resources, CBD prescribes two requirements to access the genetic resources, viz. prior informed consent and benefit sharing. On the other hand, TRIPS recognises intellectual property as a private right and did not address the issue of benefit sharing. Further, TRIPS prescribes compulsory patent protection for life forms. These cumulatively led to a situation where corporations and individuals, especially from the developed countries, appropriated the Traditional Knowledge (TK) by either patenting such knowledge itself or using such knowledge as lead for their innovation/invention without compensating or sharing the benefits of the same. This would create a situation where countries cannot implement the obligation under CBD effectively especially taking into the fact that the US, one of the major technology creator as well as market, is not a party to the CBD. Therefore, reconciliation is mandatory to avoid a conflict between two international agreements.

In 2004 developing countries came up with a more focused proposal to achieve coherence between CBD and TRIPS. According to this proposal, the major issue is that while granting patents there is no mechanism to prevent the misappropriation of genetic resources and TK. The suggested solution is to have a checklist to prevent such misappropriation by making a mandatory requirement of disclosing the source and country of origin of biological material and TK, evidence of prior informed consent and evidence of benefit sharing. These three elements are collectively known as ‘disclosure requirement’. The main submission was followed by three subsequent submissions explaining the details of implementation of three elements, which mentioned cancellation of patent in case of non-compliance of disclosure requirement. Disclosure requirements not only prevents grant of illegitimate patents but also checks the misappropriation of genetic resources and traditional knowledge. The proposal on disclosure requirements got wide acceptance even from developed countries. Switzerland and the EU accepted it in principle, but have reservation to include it in TRIPS as well as consequence of
non-compliance. However, these countries agreed to discuss the issue in the TRIPS Council. The US and Japan opposed the proposal and eventually suggested a contractual approach to the issue. According to this approach, a legal framework should be regulated through contract between the holders of TK and genetic resources and the person who wishes to access the generic material and TK. The last TRIPS Council meeting (held 25–28 October) failed to reach any consensus on the issue. However, attempts are still on to get a negotiation mandate on disclosure requirements under the Doha Rounds single undertaking. A solution in this regard is absolutely essential to address the developmental aspects of intellectual property rights.

In 2008 developing countries proposed the following modality text along with European Union.

1. Members agree to amend the TRIPS Agreement to include a mandatory requirement for the disclosure of the country providing/source of genetic resources, and/or associated traditional knowledge for which a definition will be agreed, in patent applications. Patent applications will not be processed without completion of the disclosure requirement.

2. Members agree to define the nature and extent of a reference to Prior Informed Consent and Access and Benefit Sharing.

3. Text-based negotiations shall be undertaken, in Special Sessions of the TRIPS Council and as an integral part of the Single Undertaking, to implement the above. Additional elements contained in Members’ proposals, such as PIC and ABS as an integral part of the disclosure requirement and post-grant sanctions may also be raised and shall be considered in these negotiations.

However since then there is no further progress in this regard. At the same time, nothing in the TRIPS prevents developing countries to incorporate disclosure requirements in their domestic patent laws. There are certain countries like India that have made the disclosure of origin of source of genetic material mandatory in their patent laws. These countries should incorporate the other two requirements in their patent law. Such an approach would enhance the negotiating power of developing countries. Legally speaking, there is a right as well as an obligation under CBD to incorporate disclosure requirements in their patent law. Further, there is no explicit or implicit ban on such requirements under TRIPS. Moreover, Article 28 of TRIPS permits such requirements. Such a measure would help to prevent such misappropriation at the domestic level. However, a reconciliation of the TRIPS with CBD is necessary to ensure compliance of countries who are not part of CBD such as USA.

**Article 27 .3 (b) Review**

Apart form the reconciliation of CBD and the TRIPS Agreement the review of Article 27 3 (b) includes the patenting of life forms especially patenting of microorganisms and patenting of non-biological and microbiological process of production of plants and animals. In their submission in 2003 African Group proposed the revision of Article 2.3 (b) to prohibit patents on plants, animals, microorganisms essentially biological process for the production of plants or animals, and non-biological and microbiological process for the production of plants and animals. In a subsequent submission in 2011 Bolivia also called for prohibition of plants and animals. Apart from the ethical and moral consequences of life patenting Bolivia also cited the negative consequences of Article 27.3(b) in the area of food and agriculture as well as health care.

According to the submission nearly 67% of the proprietary seed market being controlled by ten trans-national corporations, with one particular corporation controlling nearly one quarter of this market. The submission also state’s that the monopoly of patent prevents the innovation in agriculture by blocking access protected germplasam and varieties. Similarly, in health care submission cites the example of BRACA 1 and BRACA 2 gene use for the diagnosis of breast
cancer. Patenting on the genes " make it impossible for women to access alternative test or to get a comprehensive second opinion about their result. Similarly, the submission also cites the fact that 91% of the patent families pertaining to traits tolerant to climate change.

Therefore it is important that developing countries to pursue the review of Article 27.3 (b) to reverse the mandatory patenting of microorganisms and patenting of non-biological or micro-biological process of production of plants and animals.

**Geographical Indications (GI)**

TRIPS provides two level of protection to GI. Firstly, there is a general obligation to protect the obligation to protect the products other than spirits and wines. Secondly, there is an additional protection for wines and spirits. The protection to wines and spirits benefits mainly European countries. Hence, developing countries demanded similar level of protection to other products. Doha Declaration mandated negotiations on two elements, viz. to establish a multilateral system of notification and registration of GI for wines and spirits. Secondly, to have negotiations on to issues related to the extension of the protection of GI provided for in Article 23 to products other than wines and spirits. However, European proposal to have a mandatory multilateral register is opposed by the so-called new world countries like the US, Canada, Australia and Latin American countries. According to these countries the register should function as a searchable database and enforcement procedure should be grounded on national level. Firstly, the EU wants the extension of GI protection enjoyed by the wines and spirit to other products. Secondly, it is pushing for the multilateral system of notification and registration for other products. Thirdly, it wants around 41 products whose names have so far not been protected to bring back to the fold of GI protection through the claw back provision. Europe further attempts to link the breakthroughs in GI as a condition for further cuts in their farm subsidies, which is necessary for the liberalisation of agriculture trade. Any such linkage is dangerous to developing countries’ interest. This is similar trap in which the developing countries fell during the TRIPS negotiations. Even though extension of same level protection currently enjoys the wine and spirit to other products would be beneficial to developing countries, there is a need to have clear impact assessment before endorsing the European view. For instance, India currently build its GI portfolio the export potential of these GI products are minimal. Therefore, a cautious approach is needed while responding to the EU proposal. However, in 2008 India along with Africa group proposed the following way forward with regard to GI along with way forward mentioned earlier on relationship between TRIPS and CBD.

Members agree to the extension of the protection of Article 23 of the TRIPS Agreement to geographical indications for all products, including the extension of the Register.

Text-based negotiations shall be undertaken, in Special Sessions of the TRIPS Council and as an integral part of the Single Undertaking, to amend the TRIPS Agreement in order to extend the protection of Article 23 of the TRIPS Agreement to geographical indications for all products as well as to apply to the exceptions provided in Article 24 of the TRIPS Agreement mutatis mutandis.

Special and Differential treatment shall be an integral part of negotiations in the three areas above, as well as special measures in favour of developing countries and in particular least developed countries.

However, developing countries need a cautious approach on GIs and need advancement in other areas of negotiations to move forward in GIs.
Upcoming Ministerial Meeting Decisions.

Non-violation Complaints

Non-violation complaints refers to Article 64 of the TRIPS Agreement refers to Article XXIII of GATT. According to this Article, where in If any contracting party should consider that any benefit accruing to it directly or indirectly under this Agreement is being nullified or impaired or that the attainment of any objective of the Agreement is being impeded as the result of not only the failure of another contracting party to carry out its obligations under this Agreement, but also ) the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement, or) the existence of any other situation. Thus the non-violation complaint would allow a WTO Member States to approach the WTO dispute settlement mechanism even in the absence of a violation of the TRIPS Agreement. In other words developed countries like US could take India or other developing countries for using the TRIPS flexibilities such as Section 3 (d).

Article 64 of TRIPS however puts a five years for a period of five years from the date of entry into force of the WTO Agreement. It also allows further extension of the moratorium on the basis of consensus. This means any objection against the extension of the moratorium would result in the expiry of the moratorium. The last extension of the moratorium was at the Bali Ministerial conference in 2013. However in 2014 US demanded the expiration of the moratorium. Nairobi Ministerial is to take a decision with regard to the extension of Moratorium. Any objection from US or any other WTO Member States would result in expiry of the moratorium. Meanwhile developing countries made the following submission, which proposes a language for decision to extend the moratorium.

We take note of the work done by the Council for Trade-Related Aspects of Intellectual Property Rights pursuant to our Decision of 11 December 2013 on “TRIPS Non-Violation and Situation Complaints” (WT/MIN (13)/31);

After having examined the issue 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, the 10th Ministerial Conference decides that those provisions of GATT 1994 shall not apply to the settlement of disputes under the TRIPS Agreement.

LDC Extension

Least developed countries have submitted a request for the extension of the transition period with regard to intellectual property protection of pharmaceutical products.

The request seeks an extension of the transition period from 1 January 2016 to as long as the World Trade Organization Member remains a least developed country (LDC). The transition period exempts LDCs from most obligations under the WTO Agreement on Trade-related Aspects of Intellectual Property rights (TRIPS).

The current transition period on pharmaceutical products, granted in 2002 in pursuant to Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, will end on 1 January 2016. The formal request was submitted on 20 February 2015 by Bangladesh on behalf of the LDC Group, and posted officially by the WTO Secretariat on 23 February (IP/C/W/605). It will kick start a series of negotiations this year for the extension of the transition period.

[Under Article 65.1 of the TRIPS Agreement LDCs obtained 10 years of a transition period for the implementation of the Agreement including on product patent protection of pharmaceutical inventions. However, in 2001 trade ministers through the Doha Declaration on the TRIPS
Agreement and Public Health instructed the TRIPS Council to extend the transition period related to pharmaceutical products up to 1 January 2016.

This extension was done without prejudice to the possibility of further extension of the transition period with regard to the implementation of the TRIPS Agreement (general exemption) under Art. 66.1 of the TRIPS Agreement wherein the TRIPS Council “shall, upon duly motivated request by a least developed country Member, accord extensions of this period”. Under this provision LDCs obtained two extensions of the transition period with regard to the implementation of the TRIPS Agreement in 2005 to 2013, and in 2013 to 2021. Thus the extension of the transitional period on pharmaceutical products is additional to the general exemption granted in 2013 and expected to go beyond 2021.

This proposal is gaining support from various WTO member states including the EU. In a recent press release EU stated that

Key Recommendations

- Developing countries like India needs to form a broad coalition of like-minded countries and proposes changes in the TRIPS Agreement to meet the development needs under Article 71.1 of TRIPS and the Doha Ministerial Declaration.
- India needs to play an active role in the review of article 27.3 (b) and need to make proposal complementing the African Group and Bolivia.
- Developing countries needs to press for the text based negotiations on the relationship between TRIPS and CBD.
- India needs to proactively support the LDC request for the waiver of product patent pharmaceuticals.
- India needs to clearly examine the implications of non-violation complaints including its implications in the TRIPS plus context and should not give in the unjustified demands of US in other areas.