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BTIA: Study of Trips-Plus Pro visions

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ABSTRACT

"People recognize intellectual property the same way they recognize real estate. People understand what property is. But it's a new kind of property, and so the understanding uses new control surfaces. It uses a new way of defining the property".

- Michael Nesmith

Trade is one of the factors that connect two distant places of the world. No single country can declare unilaterally that it is self-sufficient in all its needs. If India needs technology, the US needs affordable IT human resource that runs their IT engines.

Considering these things in mind, India and EU sought to enter into a Free Trade Agreement (FTA), called Broad-Based Bilateral Trade and Investment Agreement (BTIA) since 2007. However, there are certain hurdles in the finalisation of this instrument. Certain provisions of this instrument have been criticised as being TRIPS-plus provisions.

The author seeks to study and investigate to what extent such provisions are against interest of India and the relevant provisions of the draft BTIA that are criticised to be TRIPS-plus arrangements.

Keywords: *BTIA, FTA, TRIPS, IPR, health, access to drugs.*

I. INTRODUCTION

A conversation or a discussion about India no more explores the old rusty picture of India, when the economy was in the shackles of the License-Raj. Consequently, the monopoly in the economy is no more order of the day. Today, many developed nations are in a hurry to enter the Indian market. They want to open joint ventures and Research and Development (R&D) projects in India with some domestic firms and entities.

With the increased reliance on the market economy and renewed faith in the private capital and resources, a developing country can not do away with influences of the World Bank and other International organisations. In the shape of opportunities, the Globalisation has inducted new opportunities to developing countries.

Today, India has come at a parity and also emerged as an important trade partner for the

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European Union (EU). With the combination of a sizeable and growing market of more than 1 billion people with a growth rate of between 8 and 10 %, it has one of the fastest growing economies in the world[2].

Although, it is confined to the study of historical data that Indian market was the closed market still there prevail some substantial tariff and non-tariff barriers that hinder trade with the EU. To do away with these trade hindrances and in order to increase their trade in both goods and services, the EU and India, entered into the Free Trade Agreement (FTA) or Broad-Based Bilateral Trade and Investment Agreement (BTIA) negotiations in 2007, which is expected to conclude by 2021[3].

Though, on its face, the negotiations sound to be pro-Indian circumstances. But, given that it also accentuates pressure upon India to step up the Intellectual Property (IP) protection in one of attributes of negotiations, the proposed free trade agreement (FTA) poses some health and human rights issues. It has left millions of people worried, about a situation without access to life-saving medicines. Across the whole under-developed and developing nations' community, the people are substantially dependent on affordable medicines produced by India, which for that reason has been dubbed the "pharmacy of the developing world"[4].

Despite the TRIPS, being in the scene as providing guidelines for minimum protection of intellectual properties, EU negotiators are putting their gruelling efforts in pressuring India to step up IP protection at the expense of public welfare and public access rights for life-saving drugs.

Thus, the proposed FTA has raised a plethora of doubts on the protection of health, once this agreement in concluded. The proposed FTA has the attributes of TRIPS-plus agreements, which once concluded, would seriously undercut India's ability to produce generic, low-cost drugs, and lead to hampering effects on access to medicines for the developing communities.

II. PROTECTION OF PATENT

The core issue involved in the BTIA concerns the protection of patents. Therefore, it is essential to take into picture the definition and national and international regimes on protection of patent. It refers to an exclusive right granted to the person who invents any new, useful, and non-obvious process or product or any new and useful improvement thereof. The right claimed by

[2] European Trade Commission, section on bilateral relations, *India* http://ec.europa.eu/trade/creating-opportunities/bilateral-relations/countries/india/ (last visited 22nd May 2021).
[3] Id.
[4]The Intellectual Property and Investment Chapters of the BTIA: Implications for Health, available at http://ec.europa.eu/health/eu_world/docs/ev_20110616_rd01_en.pdf (last visited 22nd May 2021).

the inventor are granted for a definite period of time, after it stands on the basic requirements of *novelty*, *non-obviousness* and *industrial use* or *application*.

The grant of patent and its protection is not uniform across the globe. It varies from one nation to another. More or less, there are three instruments that govern the protection of patent in the world, namely,

1. the domestic patent laws of nations;
2. the provisions of the Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement; and
3. bilateral treaties amongst various nations.

(A) National Regimes on Protection of Patent

The grant, enforcement and protection of patents are subject matter of national laws and international treaties (in case those treaties have been given effect in national laws). Therefore the protection of the rights granted thereunder differ from one nation to another. For exapmle, in Australia, the term of protection of patents is as much as 20 years[5]; under the U.S. Patent law, the protection spans to 20 years from the date on which the application for the patent is filed[6]; and under the Indian patent legislation, the term of protection extends to 20 years from the date of filing of application[7].

(B) WTO and TRIPS Guidelines

The World Trade Organisation (WTO) negotiated the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), in 1986-94 Uruguay Round, which introduced intellectual property rules into the multilateral trading system for the first time[8]. It encompasses following ares:

- Copyright and related rights;
- Trademarks, including service marks;
- Geographical indications;
- Industrial designs;

[5] Under section 67 of Patents Act 1990 of Australia, the The term of a *standard patent* is 20 years from the date of the patent, whereas, according to section 68, the term of an *innovation patent* is 8 years from the date of the patent.
[6] Section 154 of Title 35 of United States Code.
[7] Section 53 of the Patents Act, 1970.
[8] WORLD TRADE ORGANISATION, Understanding the WTO:The Agreements, *Intellectual* property: protection and enforcement http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited 26th May 2021).

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- Patents;
- Layout-designs (topographies) of integrated circuits; and
- Undisclosed information, including trade secrets[9]

The agreement deals with five cor issues pertaining to:

- application of the basic principles of the trading system and other international intellectual property agreements;
- protection of intellectual property rights;
- enforcement of these rights adequately in countries;
- settlement of disputes on intellectual property between members of the WTO; and
- special transitional arrangements during the period when the new system is being introduced[10].

Also the features of the WTO like *national treatment* (treating one's own nationals and foreigners on equal footing), and *most-favoured-nation treatment* (equality in the treatment with nationals of all trading partners in the WTO) form the part and parcel of the Agreement[11]. Another fundamental principle of the Agreement is that intellectual property protection should have its share in technical innovation and the transfer of technology. It also keeps in consideration the beneift of both producers and users and economic and social welfare should be enhanced, the agreement says[12].

III. FREE TRADE AGREEMENTS AND IP ISSUES

Generally, to facilitate trade between two countries, the Free Trade Agreements (FTAs) are entered into. Throughout the world, most of the government either opt for the FTA, or negotiate, or contemplate new bilateral free trade and investment agreements. The agreements pave the way for international integration into a global free market economy. Economic growth, reduction of poverty, good standards of living and adequate employment opportunity can be achieved through free trade and the removal of regulations on investment.

IV. BEHIND TRIPS-PLUS AGREEMENTS

In the present international community, the bilateral trade agreements have emerged as the

[9] Id.
[10] Id.
[11] Id.
[12] Id.

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main measures through which developed countries have pressurised the developing countries to adopt a more stringent intellectual property obligations than those required by the WTO TRIPS Agreement. It is the concern of the patent protection that drives the developed nations lean towards the developing countries, in order to secure an agreement in the form of the FTAs.

The member nations of the World Trade Organisation (WTO) have to fulfil the minimum standards of intellectual property protection set out TRIPS. As it is well established fact that, only a patent holder of a medicine can import or manufacture that medicine until the patent expires, unless their use falls under the exceptions and exclusions provided in the TRIPS Agreement, known as TRIPS flexibilities[13]. Also it is known to the whole world that more than 90% of the world's patents are owned by developed countries. Therefore these minimum standards are estimated by the World Bank to cost developing countries an extra US$60 billion a year as royalty payments (compared to the situation before TRIPS)[14].

(A) The Flexibilities of TRIPS - Bone of Contention

There are four broad categories of flexibility available under TRIPS, which are as follows:

1. Flexibilities related to implementation

Article 1.1 of TRIPS stipulates that:

[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

This provision leaves the room open for member nations to adopt TRIPS provisions, through the "creative implementation" of the agreement. Though TRIPS lays down the standards, it lacks in definition for their implementation, such as concepts related to patentability such as novelty, new inventions and inventiveness[15].

Also it covers the flexibilities relating to the provisions of Transitional periods. The Developing and least developed countries were given flexibility of implementation of the TRIPS. They were given the liberty to implement the provisions not with immediate effect but instead to make use of the transitional periods provided under the agreement for their benefit.

[13] *'TRIPS Plus' bilateral agreements - a threat to public health* also available at http://docs.google.com/viewer?a=v&q=cache:52EuP__uhskJ:www.twnside.org.sg/title2/resurgence/196/cover3.doc+trips+plus+agreements&hl=en&gl=in&pid=bl&srcid=ADGEEShCNoxpGrrFTa1YfkNyRLSqImEtkaEsEBaBJyh7o-aCm9Xu7cFtixPXfmSI2FMy6lVy7wF-nRJILBsHztqWilKYCGhIefMZ0sar9-uRdg-BtWKjFlvF4ajmqfDTppXjyfPM50a0&sig=AHIEtbTgP8sWFa-8-4MUrjaDIOkPCagOZg (last visited 27th May 2021).

[14] Id.

[15] Mohammed K El Said, *Public health related TRIPS-plus provisions in bilateral trade agreements,* pg. 90, available at http://www.emro.who.int/dsaf/dsa1081.pdf (last visited 27th May 2021).

2. Flexibilities related to substantive standards of protection

These flexibilities grant the autonomy to a member state to either provide or define its own standards or to provide higher standards and requirements of intellectual property protection[16]. Such flexibilities grant the state autonomy to introduce exceptions to rights conferred such as the research and experimental use and the "Bolar" exceptions[17].

3. Flexibilities related to enforcement

On one hand, Part III of the TRIPS, mandetory enforcement requirements of the agreement has been laid down. On the other hand, the agreement leaves the discretion to member states to make their national legal and judicial systems able to implement and enforce the intellectual property standards of protection as stipulated under the agreement.

4. Flexibilities of areas outside the scope of the Agreement

TRIPS is silent about some areas of intellectual property. Therefore, the areas falling outside TRIPS provide member states the right and discretion to grant protection according to their own regime, according to their priorities and national plans.

Thanks to the TRIPS provisions, many multinational pharmaceutical companies are now pushing for maintaining their monopolies on existing medicines to ensure profits, through the mechanism of a stronger intellectual property protection than provided by the TRIPS Agreement. In other words they are leaned towards 'TRIPS Plus' agreements. The protection through these agreements are made through regular unilateral pressure by the few countries such as the US and European Union who export intellectual property.

(B) Measures for Protection

After the TRIPS Agreement came in force, the developing countries gave credence to fact that TRIPS will lay down a set of uniform norms and guidelines for the regulation of intellectual property globally. But at the core of the era after TRIPS, lies the bitter reality that the developed nations are persistently making efforts to strengthen the protection of the intellectual property. The measures like the TRIPS-plus agreements and "regime shifting" have persistently been adopted by the European Union and the United States.

As far as the measure of TRIPS-plus arrangements are concerned, they can be put into either regional arrangements, like those found in the Free Trade Agreement of the Americas (FTAA), or bilateral trade agreements, like the US–Bahrain FTA, the US–Australia FTA and the US–

[16] Id.at pg. 91.
[17] Id.

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Morocco FTA.

V. HEALTH-RELATED FLEXIBILITIES UNDER TRIPS

The aspect of public health and access to medicines has relationship with the issue of strengthening of intellectual property protection. The core issues appera to be in the form of both the availability and prices of medicines and the implications for the poor, particularly those in the developing and least developed countries. It was only after the TRIPS that patent protection for pharmaceutical products has been made compulsory. Following are the health-related flexibilities under TRIPS:

- ***Compulsory Licensing.*** A compulsory licence is granted by an administrative or judicial body to a third party to exploit an invention without the authorization of the patent holder[18]. The TRIPS under Article 31 contains rules on compulsory licensing .
- ***Parallel Imports and Exhaustion of Rights.*** Parallel importation is a situation where a third party, without the authorization of the patent holder, imports a foreign manufactured product put on the market abroad by the patent holder, his licensee or in another legitimate manner in competition with imports or locally manufactured products by the patent holder or his licen-see[19].
- ***Limitation on the Grant of New Use Pharmaceutical Patents*** New use pharmaceutical patents refer to patents granted for new uses for previously known products. New pharmaceutical uses are either first pharmaceutical use (also referred to as first medical indication) or second pharmaceutical use (second medical indication)[20].
- ***Research and the Early Working Exceptions.*** Article 30 of the TRIPS Agreement establishes the general bases for exceptions to the exclusive rights envisaged under the Agreement[21]. Article 30 says:

Exceptions to Rights Conferred. Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

- ***Limiting the Extent of Test Data Protection.*** National health authorities require, for

[18] World Health Organisation, *Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks* http://apps.who.int/medicinedocs/en/d/Js4968e/6.1.1.html
[19] Id.
[20] Id.
[21] Id.

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registering new pharmaceutical products, the submission of test data relating to the quality, safety and efficacy as well as information on the composition and physical and chemical characteristics of the prod-uct. Once the data is submitted by the originator company, however, a significant number of regulatory authorities do not require companies seeking registration of generic versions of the original product to repeat the studies that are carried out by the originator company but instead rely on bioequivalence tests to grant marketing approval[22].

- ***Control of Anti-Competitive Practices and Abuse of Intellectual Property Rights.*** The TRIPS Agreement envisages a balance between the promotion of technological innovation and the transfer and dissemination of technology, in addition to a balance in the enjoyment of the benefits accruing to the users and producers of technology. These balances are contained in a number of provisions in the Agreement[23].

VI. TRIPS-PLUS AGREEMENTS AND PROVISIONS ON HEALTH ASPECTS

The TRIPS-plus health-related provisions broadly include:

- elimination and reduction of transitional periods,
- data exclusivity protection,
- extension of patent protection terms,
- restrictions on parallel importation,
- patentability of new use of known medical substances,
- restrictions on compulsory licensing,
- patenting of life forms,
- limitations on patentability criteria and
- accession to a number of international TRIPS-plus agreements[24].

In short, these provisions directly impact public health, pharmaceutical production and the availability of and prices of medicines.

VII. BTIA AND IPR ISSUES

In one of its terms, the EU-India draft FTA, covers all areas of IPRs. The hurdles created by

[22] Id.
[23] Id.
[24] Mohammed K El Said, *Public health related TRIPS-plus provisions in bilateral trade agreements,* pg. 90, available at http://www.emro.who.int/dsaf/dsa1081.pdf (last visited 27th May 2021).

IPR issues in the culmination of the FTA can be summed up in following points:

1. **Protection of 'non original databases'**. Under Article 2.2 of the FTA, the attempt has been made by the EU to accentuate the protection of 'non original databases' in India, which has been apparently rejected by the Indian government[25]. One of the reasons behind such rejection is that the sui generis protection of such databases gives birth to rights (also including 'extraction right') that may hamper the access to knowledge in the public domain.

   Given, the access to collected data has an essential role to play in an information-based society and also that the European Commission casts serious doubts about the necessity of the sui generis protection established by Directive 96/9/EC of the European Parliament, such demand by the EU raises the question about the terms of the FTA[26]. The terms of the draft agreement under article 2.2, also exhibits the intention of the EU to create sui generis exclusive rights for a particular set of empirical data (such as data obtained as a result of clinical trials to demonstrate the efficacy and safety of a drug or agrochemical product)[27].

2. **Technology Transfer.** It has been observed by the developing countries, particularly India, the TRIPS Agreement is lacking in ensuring an effective transfer of technology on fair and reasonable terms[28]. Even in the EU-India draft FTA, there seems absence of mechanism that can enhance technology flows from Europe to India. The terms of the draft agreement, have made such transfer contingent to the Parties' 'exchange of views and information on their domestic and international policies affecting transfer of technology' and to the creation of an 'enabling environment for technology transfer in the host countries, including issues such as the relevant legal framework and development of human capital'[29].

   In simple terms, this general declaration compels India to create the appropriate conditions

[25] Carlos M. Correa, *Negotiation Of A Free Trade Agreement European Union-India: Will India Accept Trips-Plus Protection?*, pg. 3, available at http://docs.google.com/viewer?a=v&q=cache:mAowP64-ldUJ:www.eed.de/dyn/download?entry%3Dpage.en.pub.de.365+EU+INDIA+FTA+TRIPS+PLUS&hl=en&gl=in&pid=bl&srcid=ADGEESj4VtNJUUom3SVt2C_zeyWDyMbAIJpvKHYZbcIXG0ay-94vD46ZyZ6owFpWynTsihfBjZfqjAs5bPPN0B-vOLEFCvCWku_F5gx8JIyGrIqCZvjmPgx-4Wjyib9u2SWjc_xB3nVt&sig=AHIEtbTuX4OjL-EHGSQva7C2f-awzJ_xWw&pli=1

[26] DG INTERNAL MARKETAND SERVICES WORKING PAPER, *First evaluation of Directive 96/9/EC on the legal protection of databases, Brussels*, pg. 12 December 2005, available at http://ec.europa.eu/internal_market/copyright/docs/databases/evaluation_report_en.pdf. (last visited 27th May 2021).

[27] Carlos M. Correa, *Negotiation Of A Free Trade Agreement European Union-India: Will India Accept Trips-Plus Protection?*, pg. 4, available at http://docs.google.com/viewer?a=v&q=cache:mAowP64-ldUJ:www.eed.de/dyn/download?entry%3Dpage.en.pub.de.365+EU+INDIA+FTA+TRIPS+PLUS&hl=en&gl=in&pid=bl&srcid=ADGEESj4VtNJUUom3SVt2C_zeyWDyMbAIJpvKHYZbcIXG0ay-94vD46ZyZ6owFpWynTsihfBjZfqjAs5bPPN0B-vOLEFCvCWku_F5gx8JIyGrIqCZvjmPgx-4Wjyib9u2SWjc_xB3nVt&sig=AHIEtbTuX4OjL-EHGSQva7C2f-awzJ_xWw&pli=1 (last visited 27th May 2021).

[28] WT/GC/W/147, 18 February 1999, available at www.commerce.nic.in/D644e.doc (last visited 28th May 2021).

[29] TWN- Third World Network, EU demands in BTIA could adversely affect access to drugs, http://www.twnside.org.sg/title2/wto.info/2009/twninfo20090612.htm (last visited 28th May 2021).

for the transfer of technology to occur, without touching upon the issue of obligation on the EU.

Further, the draft FTA lacks in the provisions aimed at curbing the misappropriation ("bio-piracy") of traditional knowledge and genetic resources[30].

3. **Parallel Imports:** Parallel imports serve as an important mechanism to allow access to IPRs-protected products, essentially to allow access to medicines that may be otherwise unaffordable. Regarding this, article 4 of the EU-India draft FTA confirms the Parties' right to provide for parallel imports. However, the final proviso which uses the phrase *'subject to the provision of the TRIPS Agreement'* raises some concerns. Article 6 of the TRIPS Agreement exempts exhaustion, under national laws, from any challenge under the WTO dispute settlement mechanism.

4. **Copyright and related rights.** The Copyright Act, 1970 provides a strong protection to copyright, though India never ratified the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (Rome Convention), WIPO Copyrights Treaty and the WIPO Performances and Phonograms Treaty. Further, the TRIPS Agreement does not obligate all WTO members to comply with the Rome Convention. On the other hand, the EU-India draft FTA requires accession by India to such treaties.

   Though both India and EU have agreed to commit themselves to recognize authors' rights for 60 years post mortem auctoris, there seems a disagreement regarding the EU proposal to eventually count the term of protection for related rights, which ensues extension of the term of protection as it seeks minimum 50 years term for related rights, which it wants to be counted from a different date (such as the first publication or communication of a performance or of a phonogram).

   Also, the EU has proposed a provision obligating the Parties to recognize a 'resale right' for original works of art, which has not yet been agreed by India. Section 53A of the Copyright Act, 1957 recognizes this right in India but subject to certain limitations.

   Lastly, conflict persists regarding *protection to digital works*. India seeks to maintain a delicate balance between public and private interests ensuring that the public domain is preserved from illegitimate appropriations[31]. The provisions proposed by the EU, such as

[30] Id.

[31] Carlos M. Correa, *NEGOTIATION OF A FREE TRADE AGREEMENT EUROPEAN UNION-INDIA: WILL INDIA ACCEPT TRIPS-PLUS PROTECTION?*. Available at _https://www.oxfam.de/system/files/20090609_negotia tionofafreetradeaggrementeuindia_218kb.pdf (last visited 2nd June, 2021).

regarding 'technology protection' (which seek to limit usage of digital media or devices without authority) and, particularly, 'anti-circumvention' measures (which prevent a person from utilizing technologies and equipment in order to bypass technical protections, such as encryption methods) are bound to limit the use of copyrighted works even for legitimate purposes[32].

This type of measures, if broadly defined, may drastically limit access to knowledge and put a significant obstacle to the implementation of educational policies. In a long run such proposal will limit access to knowledge and create hurdle in implementation of educational policies.

5. **Trademark Issues.** The EU insists on accession to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (1989), and compliance with the Singapore Treaty on the Law of Trade Marks (2006) and the Trademark Law Treaty (1994). India joined the Protocol in 2013. But compliance with other treaties may restrict the intervention of the national office in the registration of marks of foreign origin. For the same reason it is resisted in many countries by local trademark agents.

   India, therefore proposed amendments to articles 6.3 ('Well-known trademarks) and article 6.4 ('Exceptions to the rights conferred by a trademark') in light of these concerns.

6. **Geographical indications.** There seems to be lack of consensus between the EU and India on GIs protection. However, the Indian Geographical Indications of Goods (Registration and Protection) Act, 1999 allows the government to confer a TRIPS Article 23-type protection to all GIs of Indian origin thus Indian law already is TRIPS-plus in this respect[33].

   The EU has proposed to establish a mechanism for the addition of new GIs, particularly for use of GIs in Internet and organizational matters, which is poised to be a significant achievement for European countries, who have always spearheaded the agenda of expansion of the international protection of GIs.

7. **Patent protection.** The provisions regarding patent protection are mixed bag of beneficial and restrictive provisions under the Act. Article 9.1 of the BTIA obligates compliance with provisions of three conventions, namely, the Patent Cooperation Treaty (1970); the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977); and the Patent Law Treaty (2000) which harmonizes certain procedural aspects of patent law and which has not been adhered to by India.

[32] Id.
[33] Id.

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The first two are in force in India since 1998 and 2001 respectively. But India has not adhered to the Patent Law Treaty.

Several beneficial aspects of the BTIA can be summed up as follows:

It takes into consideration 'importance of the Doha Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 by the Ministerial Conference of the WTO[3435]. Further article 9.2.1 casts an obligation on the parties to ensure consistency with this Declaration.

- It obligates the Parties to implementat and to respect the WTO Decision of August 30, 2003, which allows for the exportation of pharmaceutical products under compulsory licenses to countries without manufacturing capacity in pharmaceuticals. This has been fulfilled by enactment of legislation by both parties.
- It also obligates both parties to take the necessary steps to accept the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005 (which has introduced permanently into the TRIPS Agreement additional flexibilities to grant special compulsory licences for the export of medicines).
- BTIA further does not intend to impair the capacity of the Parties to promote access to medicines'[36].

However, the EU also seeks to induct TRIPS-plus provisions, which are strongly objected to by India, as it threatens to limit access to drugs:

- Under Article 9.3 of the BTIA, India has been obligated to extend the monopoly accorded by a patent for up to five additional years as a compensation for the time required for the marketing approval of a medicinal product[37]. Such provision imperils time-bound the entry of generic competition, thus restricting affordability of drugs.
- Article 10 imposes an obligation on India to create a sui generis protection for test data submitted for the approval of pharmaceutical as well as agrochemical products. However, such forms of protection are not required by the TRIPS Agreement and

[34] The Declaration confirms the 'flexibilities' available under the TRIPS Agreement. Particularly, paragraph 4 provides 'that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to 'medicines for all'.
[35] Under Article 9.2.1 of BTIA draft.
[36] Supra note 30.
[37] This provision is similar to the concept of 'supplementary protection certificate' applied in the European context.

are strongly against interest of India. Such provision threatens to create market exclusivity after the approval of a product, thereby isolating it from generic competition.

Further, given that provision does not specify the duration of the proposed right, if adopted, it may imperil the access to low-priced drugs by Indian consumers.

8. **Breeders' rights.** The Indian Protection of Plant Varieties and Farmers' Rights (PPVFR) Act provides for registration of extant and farmers' varieties and benefit sharing provisions to compensate farmers' for their innovations.

   The BTIA, under article 11, obligates for 'co-operation to promote and reinforce the protection of plant varieties based' on the Convention on the Protection of Plant Varieties (UPOV 1991). Also, it makes a specific reference tto article 15(2) of UPOV with regard to the possibility of introducing an exception for the use of seeds saved by farmers (a right explicitly recognized under Indian law).

9. **Protection of traditional knowledge and genetic resources.** India has always taken strong stand for curbing the misappropriation ('biopiracy') of traditional knowledge and genetic resources. But the draft BTIA is silent on this subject. FTA can be availed of as an opportunity to ensure full compliance from EU with the Convention on Biological Diversity and, also to insist for an obligation for disclosure of the origin of biological materials claimed in a patent application. Such provisions have already found place in the CARIFORUM EPA[38].

VIII. CONCLUSION

With the TRIPS Agreement coming into force, the world has witnessed several fundamental changes to the global regulation of intellectual property. Among other aspects, TRIPS has most severely affected pharmaceutical patents. The situation seems to be unsettled. Before the TRIPS regime, theere was threat to the international trade. But after that regime, the global community is facing the issues of public health.

The world community is striving to maintain a balance between the IP protection and health issues. But the individual states and some global entities, like EU, are in a hurry to enhance the protection of the intellectual property at the cost of the public health. Some of the European Union's demands for higher intellectual property (IP) standards, if adopted, may obstruct the supply of low-cost generic medicines. If that situation occurs, India, being home to a big chunk

[38] Under Article 150.

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of populations of poor people in the world, will face the grave situation of the exclusion of the poor from access to essential products, such as medicines and input for agricultural production.

So the BTIA, being firm on the touchstones of a TRIPS-plus instrument, India should rethink before finalising and adopting its controversial provisions, keeping in mind the public health issues.

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