Unveiling the Darker Side of The Free Trade Agreement on Access to Medicines: Critically Analyzing EFTA-India Free Trade Agreement

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INTRODUCTION

"*Medicines should be available based on the needs of the people rather than the ability to pay"*
-World Health Organization

The health of an individual should be unequivocally prioritized, as good health enables better performance and efficacy in all endeavours. Thus, universally, attaining a better standard of health is considered as an indispensable part of human rights, and the states are obliged to ensure and promote public health without any discrimination in order to ensure the "*highest attainable standard of health"* for every individual.[1] Medicines and vaccines are necessary to safeguard the lives of individuals and to fight against epidemics,[2] Thus, accessing those medicines is essential to attain better health.[3] The access to medicines refers to the availability of affordable and quality therapeutics to every citizen whenever necessary for the treatment of diseases.[4]

Earlier, pharmaceutical products were not included under patent protection for fear that monopolistic power would charge exorbitant prices. The Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter TRIPS Agreement) was introduced to unify the Intellectual Property (hereinafter IP) rules globally and mandates that every state which are member of TRIPS has to follow the provisions and has obliged member countries to provide product patents for drugs developed. The provision of product patents has drastically affected the production of generic versions of pharmaceutical products. The Least Developed Countries (hereinafter LDC) were given a waiver provision for pharmaceutical products till 2016 and also

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[1] Constitution of the World Health Organization, pmbl., July 22, 1946.
[2] Sitanshu S K, Himanshu S P, *Concept of Essential Medicines and Rational Use in Public Health*, 35(1) Indian J. Community Med 10 (2010).
[3] International Covenant on Economic, Social and Cultural Rights, 1966, art. 12.2(c), Dec. 16, 1966.
[4] Committee on Economic, Social and Cultural Rights, General comment no.14: *The Rights to the Highest Attainable Standard of Health*, para. 12, UN Doc. E/C.12/2000/4 (2000).

provided with an option of further extension of the period if required. The remaining countries are provided with the provisions of flexibility to tackle the concern of inequity in accessibility.[5] Later, the HIV/AIDS pandemic realized the negative impact of product patents as people from least-developed and developing countries were struggling to access drugs that were in the market due to exorbitant prices. In this context, the Doha Declaration was signed to end this inequity by introducing and reaffirming sufficient TRIPS flexibilities in ensuring access to affordable and quality drugs. The developed countries started with a new trend of engaging in bilateral agreements in the form of FTAs with various developing countries. Through these FTAs, the developed countries incorporate stronger IP standards, making the TRIPS a minimum standard. These higher standards of IP provisions were referred to as TRIPS-plus provisions, which have the ability to undermine the developing countries' right to claim these flexibilities, as these developed countries stand in a dominant position.

As India is known as a hub for manufacturing generic versions of pharmaceutical products, it has now signed an FTA with four-nation European Free Trade Association (hereinafter EFTA) by incorporating IP provisions. These TRIPS-plus provisions will threaten the future production of generic drugs, affecting access to pharmaceutical products.

When the world struggles to rectify persistent disparities that still exist in the field of equitable access to affordable medicine following the aftermath of the Covid19 pandemic, developed countries are trying to fortify the exclusive power of inventors through FTA.

THE BACKGROUND

The WHO emphasized the importance of ensuring access to affordable healthcare facilities for the attainment of the best possible health standard for all without any sort of exclusion based on their socio-economic or geographical status. Also, several international conventions mandate the state's responsibility to ensure that individuals are able to attain the health standards. However, there exist various kinds of hurdles to access to medicines, such as economic, geographical, regulatory, supply chain, health system, intellectual property protection, and more. In that the role of intellectual property provision stands high. Even though intellectual property protection of pharmaceuticals acts as a catalyst for producing medicines that are much needed for a society to treat diseases, it also has some remarkable effects on

[5] UNAIDS Issue Brief, *The Potential Impact of Free Trade Agreements on Public Health* (May 2012), https://www.unaids.org/sites/default/files/media_asset/JC2349_Issue_Brief_Free-Trade-Agreements_en_0.pdf

access to drugs.[6] Many countries before the TRIPS Agreement were reluctant to incorporate IP provisions into pharmaceutical products due to the fact that monopolistic power over medicines led to exorbitant prices and undermined the accessibility to affordable medicines.[7] Thus, facilitates the production of generic versions that are available to the public at lower prices and maintains healthy competition. But, the provisions for patenting both the process and product of the new drugs were incorporated through the TRIPS Agreement, and the member countries were under the obligation to implement the same after the allotted transition period for each country. Even though certain flexibilities were incorporated to minimize the negative effects of product patents on medicines, they appeared to be insufficient in various circumstances. Especially, during the HIV/AIDS pandemic, the hardships encountered by developing countries and LDCs in eliminating the pandemic pointed out the inefficacy of existing flexibilities to ensure timely access. This mandates the WTO to sign the Doha Declaration to reaffirm that the people are able to attain the possible health standard as a human right through access to essential healthcare facilities, which has to be prioritized when it conflicts with the exclusive rights of the inventor in a public health emergency.[8] The declaration reaffirmed the flexibilities by offsetting patents to promote the accessibility of affordable medicines.[9] The developed countries are trying to adopt FTAs with the motive to establish higher IP protections and to restrict the usage of TRIPS flexibilities, negatively affecting the individual's basic right to access.[10]

The Covid19 pandemic has unfolded the existing disparities in the field of equitable access to healthcare services, which affect not only LDCs but also the entire population. Globally, millions have lost their lives, and half a billion people were infected with the virus due to delayed access to patented pharmaceutical products during the pandemic. It was stated that "*no one is safe from Covid19 until everyone is safe,*" a concrete reality during the pandemic.[11] Thus, due to the disparities and difficulty in claiming TRIPS flexibilities even during the global

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[6] Marion Motari, et.al., *The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement*, 21 BMC Public Health, 490 (2021).

[7] Many developed countries were reluctant to pharmaceutical product patent. For example, Italy, Switzerland, and Swedan until 1978, Spain until 1992 does not allow patent to medicines. Available at: Sanya R. Smith, *Intellectual Property in Free Trade Agreements*, Third World Network (May 06, 2024, 05:31 AM), https://www.twn.my/title2/books/SanyaFTA.htm.

[8] World Trade Organisation, *Declaration on the TRIPS agreement and public health*, Doha WTO Ministerial: TRIPS WT/MIN(01)/DEC/2, Para 4 (2001).

[9] Sanya R. Smith, *supra* note 8, at 8

[10] *Id.*. at 3

[11] Dr. Tedros, Dir. Gen., World Health Org., *Statement: No One is Safe Until Everyone is Safe- Why We Need a Global Response to Covid19*, UNHCR, https://www.unhcr.org/in/news-releases/statement-no-one-safe-until-everyone-safe-why-we-need-global-response-covid-19 (last visited May 07 2024)

pandemic, the developing countries and LDCs demanded for waiving IP rules on medicines, vaccines, and medical technologies[12]. After prolonged negotiation in July 2022, WTO approved a three-year waiver for only Covid19 vaccines. The developing countries argued that waiver of vaccines alone would not be sufficient to meet future health challenges.[13]

When the WHO and public health advocates fight to rectify the disparities that still exist in the field of equitable access to affordable medicine following the aftermath of the Covid19 pandemic, developed countries are trying to extend the exclusive power of patent holders through FTA.

IP REGULATION IN FREE TRADE AGREEMENTS

An FTA is an agreement entered into by two or more countries to enhance trade by eliminating barriers to trade like tariffs and quotas.[14] Countries impose tariffs and duties on imports and exports through FTA by reducing trade barriers.

Even though these treaties seem discriminatory, they have been allowed under the WTO through the Most-Favoured Nation (hereinafter MFN) treatment.[15] The developed countries were showing an interest in adopting higher IP standards. Therefore, they create a global ratchet for higher IP standards through FTAs. They attract developing countries to sign bilateral agreements by giving preferential access to their markets.[16] Also, there is a notion behind

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[12] India and South Africa jointly submitted a proposal demanding waiving off IP rules on pharmaceutical products to prevent the spread of Covid19 pandemic on October 2, 2020. The proposal suggest for; '*In these exceptional circumstances, we request that the Council for TRIPS recommends, as early as possible, to the General Council a waiver from the implementation, application and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19.'*
Available at; WTO, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True (last visited May 6, 2024)

[13] WTO, *TRIPS Council welcomes MC12 TRIPS waiver decision*, discusses possible extension Available at https://www.wto.org/english/news_e/news22_e/trip_08jul22_e.htm#:~:text=At%20a%20meeting%20of%20the,production%20and%20supply%20of%20COVID, (last visited May 6, 2024)

[14] Victoria Masterson, *Explainer: What is the European Free Trade Association?*, World Economic Forum (Mar. 20, 2014, 03:45PM), https://www.weforum.org/agenda/2024/03/efta-india-free-trade-deal/

[15] MFN treatment requires member countries to have most favoured tariffs and treatments on a product during the time of import and export to other countries not necessary to be a WTO member country. Also those favourable treatments must be extended to all other member countries. Thus, through MFN treatment it prohibits any such discrimination provided on the same product at different countries.
Divesh Pandey and Meera Unnikrishnan, *Free Trade Agreements by India: Review and Implications for Future*, Research and Policy Insights on Financial Markets and Economy, (May 07, 2024 04:061AM) https://www.iima.ac.in/sites/default/files/2023-03/MCFME_FTAs.pdf

[16] Henning G. Ruse-Khan, *The International Law Relation between TRIPS and Subsequent TRIPS-Plus Free trade Agreements: Towards Safeguarding TRIPS ding TRIPS Flexibilities*? 18 J. INTELL. PROP. L. 325 (2011).

imposing stricter IP standards that it will help increase foreign direct investment, accelerate research and development, and promote innovation.[17]

These provisions incorporated by the developed countries are called 'TRIPS-plus' provisions because these are an extended version of IP protection under the TRIPS Agreement. While negotiating FTAs, the developing countries do not have any voice to give any input to the treaty.[18] On realization that the developed countries do not make enough profit from the pharmaceutical industry due to TRIPS regulation, they took these FTAs as a better opportunity to raise higher IP standards, and other parties are obliged to compulsory adoption of terms of these bilateral treaties.[19]

There exists an uncertainty regarding whether the TRIPS-plus provision, which is imposed by a member country, will extend to all members of WTO in the future under the MFN clause. Article 4 of this agreement states that, "*with regard to the protection of intellectual property, any advantage, favor, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members.*"[20]

DARKER SIDE OF FTA ON EQUITABLE ACCESS

The WHO pointed out that "*Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries.*"[21] The report of the United Nations Special Rapporteur on the Right to Health also pointed out, "*Developing countries and LDCs should not introduce TRIPS-plus standards in their national laws. Developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health.*"[22]

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[17] Rohit Malpani, *All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines*, Oxfam Briefing Paper, March 2007 (May 07, 2024 05:11AM) https://oxfamilibrary.openrepository.com/bitstream/handle/10546/114080/bp102-all-costs-no-benefits-trips-210307-en.pdf%3Bjsessionid%3D089750820CF675173F0C3204C369D63F%3Fsequence%3D1

[18] Christine Haight, *TRIPS-Plus Trade and Investment Agreements: Why More May Be Less for Economic Development*, 35(4) U. Pa. J. Int'l L 1061, 1064 (2014)

[19] M. Ayilath, *Free trade agreements and access to medicines: need for regulation* (June 01, 2013) http://dx.doi.org/10.2139/ssrn.2273275

[20] Agreement on Trade Related to Intellectual Property Rights, art. 4.

[21] WHO, Report of the Commission on the Intellectual Property Rights, Innovation and Public Health, Recommendation 4.26 (2006), https://iris.who.int/bitstream/handle/10665/43460/a88438_eng.pdf?sequence=1

[22] U.N. Human Rights Council, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, U.N. Doc. A/HRC/11/12 (2009).

The TRIPS-plus provision directs members to the FTAs to adopt IP rules that are beyond the TRIPS Agreement. These extended IP provisions undermine the right to claim flexibilities by the countries to ensure accessibility. The provisions under FTAs that act as barriers to access include extending patent durations, patent registration linkage, prohibition of parallel imports, preventing patent oppositions, and limiting the grounds for compulsory licensing.

1. Extending patent duration:

   Incorporating extension of patent terms beyond 20 years through various reasons is a common trend in FTAs. Commonly, they incorporate a clause that mandates the signatory parties to "*compensate for unreasonable delays that occur in the grant of the patent.*" Unfortunately, this delay in procedure cannot be for a specific time period; it varies. For example, The Central American Free Trade Agreement (hereinafter CAFTA) includes a provision to compensate for the delays that may arise during the grant of patents unreasonably.[23] Also, most of the US entered FTAs incorporate patent extension through the clause, "*With respect to patents covering pharmaceutical products, each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.*"[24] The TRIPS Agreement has not provided an option in order to offset for the delay that may occur during the grant of a patent and for market approval. Whereas, the big pharmaceutical companies, by way of the insertion of these provisions into FTAs, try to maintain the monopolistic power over the patented medicines even after the patent period.[25]

2. Data exclusivity:

   To get market approval for a drug, certain information has to be submitted to the drug regulatory authority regarding clinical trials, which are used to prove the safety, efficacy, and quality of the pharmaceutical products, especially vaccines and medicines. In case of approval of generic versions of these products, they need not do all the clinical trials again; instead, they need to prove the bioequivalence of their molecule.[26]

[23] Central American Free Trade Agreement (CAFTA), art. 15.9.6(a).
[24] Free Trade Agreement between the United States of America and the Kingdom of Morocco, [2004], U.S.-Mor., art. 15.10.3
[25] M. Ayilath, *supra* note 20 at 24
[26] *Id.* at 25.

TRIPS Agreement also provided with a provision to protect and safeguard undisclosed data, which is required to be disclosed for market approval from unfair commercial use.[27] The member state is also under the duty to adopt required measures to protect this data, with the exception of public safety. Under Article 39.3 of this Agreement, the developed countries, especially the big pharmaceutical companies from these countries, try to incorporate the provision of 'data exclusivity'[28] under FTAs which prohibits those generic companies from accessing the data to prove the equivalence of generic versions of drugs.[29] Because, the TRIPS Agreement does not restrict generic companies from making use of the trial data for their market approval. The exclusivity provision, in reality, creates hurdles in the market for the entry of competitors and also restricts the issuance of compulsory licenses.[30]

3. Patent registration linkage:

Patent linkage creates a crucial relation between IPR and pharmaceutical regulation with respect to the approval of a generic version. It is the process of connecting the grant of drug marketing approval and the status of generic versions to the status of original branded equivalents.[31] Patent linkage can be on market authorization, pricing and reimbursement decisions, procurement, or any regulatory approval. Such linkage aims to block the generic version's entry soon after the patent term expires, specifically undermining the *bolar exemption*. Thus, it affects access to affordable drugs in time as it delays healthy competition. In Europe, this patent linkage is considered to be unlawful due to its negative effects on the healthcare system.[32]

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[27] TRIPS Agreement, *supra note* 21, at art. 39.3.

[28] Data exclusivity refers to protection of clinical test data report which is submitted to the drug regulatory authority from generic manufacturing company for a specific period. The period refers to 8 year protection from generic applicant from being referring and in case of market exclusivity 10 years has been given after which only generic versions can be marketed.
Available at European Commission, *Pharmaceutical Sector Inquiry Final Report*, DG Competition, July 08, 2009, https://competition-policy.ec.europa.eu/system/files/2022-05/pharmaceutical_sector_inquiry_staff_working_paper_part1.pdf

[29] Sanya R, *supra note* 10 at 11

[30] M. Ayilath, *supra note* 20 at 21

[31] European Commission, *Pharmaceutical Sector Inquiry Final Report*, DG Competition (July 08, 2009) https://competition-policy.ec.europa.eu/system/files/2022-05/pharmaceutical_sector_inquiry_staff_working_paper_part1.pdf

[32] Position paper, *The anti-competitive effects of patent linkage*, medicines for Europe, (May 2019) https://www.medicinesforeurope.com/wp-content/uploads/2021/03/Medicines%20for%20Europe%20Position%20Paper%20On%20Patent%20Linkage%20-%20May%202019.pdf

4. Prohibition of parallel importation:

   Parallel importation means legally importing the patented drug without the patent holder's authorization to another market, which is also known as "*gray-market imports.*"[33] The doctrine of exhaustion principle, provided that on selling the patented products in the market, the right of the patent holder over the products will exhaust and he does not have the right to its further movement. Thus, through the TRIPS Agreement, parallel imports are allowed as they help in access to affordable medicines.

   The US has its national exhaustion policy, which incorporates the patent holder's authorization for importing the patented products ever after the rights get exhausted.[34] Thus, recently developed countries signed FTAs by incorporating national exhaustion policies to prevent the scope of parallel importation.[35]

5. Preventing patent oppositions:

   The pre-grant opposition has an important role in safeguarding public health by preventing the grant of patents for unwanted medicines and ever greening. TRIPS allows anyone to file pre-grant opposition if it seems relevant before the grant of patent. Usually, the process of pre-grant opposition is a cheaper and simpler procedure when compared to post-grant opposition. These TRIPS-plus provisions in the FTAs restrict the pre-grant opposition.[36]

6. Limiting the grounds of compulsory licensing:

   Compulsory licensing is adopted as a vital mechanism for resolving the adverse effects of patents on access to pharmaceutical products in case of health emergencies.[37] The member countries have the right to determine the grounds for issuing compulsory licenses under the Doha Declaration.[38] Through FTAs, developed countries may try to

[33] Susan K. Sell, *TRIPS-Plus Free Trade Agreements and Access to Medicines*, 28(1) Liverpool Law Review 41, 61(2007).
[34] Sanya R, *supra note* 10 at 21
[35] Susan K, *supra note* 34 at 61
[36] *Id*, at 64
[37] MSF, *The importance of pre-grant patent oppositions in increasing access to medical products*, MSF Access Campaign (July 25 2022) https://msfaccess.org/sites/default/files/2022-07/IP_TechBrief_India%20Pre-Grant%20Opposition%20FAQ_Eng_July2022.pdf
[38] Doha Declaration, *supra note* 9, Para 5.b.

limit the grounds to issue compulsory licenses. For instance, the FTAs limit the grant of issuing compulsory licenses only in 'national emergency or any other extreme urgency' as shown in the US FTA signed with Singapore.[39] Thus, the incorporation of such languages will erode the true intention of flexibility and generic competition.[40]

Due to the lack of adequate health insurance policies by governments to mitigate the healthcare emergencies, the patients are compelled to incur all the expenses out-of-pocket. When the access to healthcare facilities charges exorbitantly high, the patients in low and middle income countries disproportionately shoulder the burden.[41] However, the primary motive driving the developing countries to engage in such FTAs even though it suffers bitterness is to get access to foreign markets.[42]

EFTA –INDIA FTA; RECENT CHALLENGES IN ACCESS

On March 10, 2024, India signed an FTA with EFTA[43], India's first FTA with developed nations. They have signed a comprehensive Trade and Economic Partnership Agreement (hereinafter TEPA) after 21 rounds of negotiation, which started in 2008.[44] This FTA has been negotiated for 15 years, with a USD100 billion investment commitment and 1 million direct employment opportunities. It also provides access to the market more easily and removes import tariffs on goods that are from EFTA countries.[45] This agreement incorporates rules relating to IP protection under Chapter 8, along with certain clauses in Annexure 8A and *Record of Understanding on IP*. While going through the supplementary documents, in the future, there is a threat of undermining the provisions of TRIPS flexibilities related to access.[46] Through this FTA, there is a chance of undermining the provision of pre-grant opposition, an important tool to prevent the ever greening of patents over medicines. The big pharmaceutical companies always try to extend their patent monopoly by making any improvements or modifications to the existing drugs. In the supplementary document, Article 11.7 of Annexure

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[39] United States -Singapore Free Trade Agreement, [2003], art. 16.7(6)(b).
[40] Shayerah Ilias, *Intellectual Property Rights and Access to Medicines: International Trade Issues*, Congressional Research Service (June 14, 2010) https://crsreports.congress.gov/product/pdf/RL/RL34292
[41] Sanya R, *supra note* 10, at 16.
[42] M.Aliyath, *supra note* 20, at 47.
[43] The four nation EFTA includes Iceland, Liechtenstein, Norway and Switzerland. EFTA found in 1960 aimed economic benefit and to promote free trade.
[44] India free trade agreement, https://www.efta.int/trade-relations/free-trade-network/india (May 09, 2024, 07:15AM)
[45] India-EFTA Trade and Economic Partnership Agreement, Ministry of Commerce & Industry (Mar.10, 2024 3:09PM) https://pib.gov.in/PressReleaseIframePage.aspx?PRID=2013169
[46] MSF response to signing of EFTA-India trade agreement, MSF Access Campaign, Intellectual Property and Trade, (Mar. 12, 2024) https://www.msfaccess.org/msf-response-signing-efta-india-trade-agreement

8 gives the power to the competent authority to *swiftly reject prima facie unfounded oppositions.*[47] The patent controller, the competent authority, is given the right to immediately dismiss pre-grant opposition on the grounds of lack of initial evidence or justification to support the claims. This arbitrary power to the Controller will definitely be a threat to the generic production of medicines because there is a chance of extension of the patent term with minor modifications.[48] The Indian Patent Act has already taken a step to undermine the pre-grant opposition through Draft Patent Amendment Rules, 2023, which poses a great concern.[49]

Even though the final FTA does not speak about data exclusivity, a provision was left in the Record of Understanding to discuss matters relating to undisclosed information one year later after entering into consultation.[50] The big pharmaceutical companies in developed countries always try to incorporate TRIPS-plus provisions, especially data exclusivity through FTAs. Thus, it is anticipated that the recent step to signing into FTA makes access to affordable medicines more difficult.[51]

Another concern present in the FTA is related to the working of patents, which states that,

"No Party shall require patent owners to provide annual disclosures of information concerning the working of a patent. Where a Party does provide for periodic disclosure of information concerning the working of a patent, the periodicity shall not be less than 3 years, and confidential information, including information of commercial value, contained in such disclosure may not be published."[52]

The annual report on the workings of the patent and its information will be a great tool to ensure patented products are made available to the public. Eliminating the same provision by extending the time for disclosure to 3 years will definitely negatively affect accessibility, which is against the primary object of this Agreement. However, incorporating the provision of 'not

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[47] Annex 8A Protection of Intellectual Property https://www.efta.int/sites/default/files/documents/legal-texts/free-trade-relations/india/8.A%20-%20Protection%20of%20Intellectual%20Property.pdf

[48] MSF Comments on intellectual property provisions in the final agreement of India-EFTA Agreement concerning the impact on access to medicines (Mar.12, 2024) https://www.msfaccess.org/msf-comments-intellectual-property-provisions-final-agreement-india-efta-agreement

[49] Ramesh Shankar, *Concern on new patent rules*, pharmabiz.com (Mar. 06, 2024, 08:00) https://www.pharmabiz.com/ArticleDetails.aspx?aid=166746&sid=3#:~:text=A%20large%20number%20of%20civil,potential%20to%20significantly%20hinder%20access

[50] "....In implementing Article 15, Parties agree to enter into consultations, one year after entry into force of this agreement, to discuss issues relating to protection of undisclosed information from unfair commercial use…", Record of Understanding Relating to the Annex on IPR of the Trade and Economic Partnership Agreement between the EFTA States and the Republic of India, https://www.efta.int/sites/default/files/documents/legal-texts/free-trade-relations/india/Record%20of%20Understanding%20on%20IPR.pdf

[51] *Supra note* no. 46

[52] *Supra note* no. 45 at art. 12.1.

worked patent' on the ground of imported patented product[53] will hinder the chance of the government to claim compulsory licensing in time. [54]

The signing of EFTA- India FTA and the introduction of the Draft of Indian Patent Amendment Rules 2023 make way to establish more stringent TRIPS-plus provisions that undermine the flexibilities regarding public health. Thus, it will negatively affect India's pharmaceutical generic industry domestically and internationally.

CONCLUSION

The TRIPS-plus provisions in the FTAs have brought stricter IP protections and challenges to access to medicines. India-EFTA deal also incorporates several IP rules, such as prevention of pre-grant oppositions, upbringing of data exclusivity, extending annual patent report submission to once in three years, etc, which undermine the public health safeguards ensured by the TRIPS Agreement. These provisions will definitely affect the production of generic versions in the coming days. Under the guise of a huge investment, job creation, and expanded access to foreign markets, the potential threat to access to patented drugs and health risks remains obscured. Thus, the India-EFTA free trade agreement will be a great threat to generic competition and will undermine the right to claim TRIPS flexibilities.

Health is not something that people should attain at the whims of others; rather, it is a fundamental human right of an individual guaranteed by the state. Therefore, it is the responsibility of the state to ensure each and every person achieves optimal health without being discriminated against. Therefore, governments must anticipate all potential risks that may occur in the future when entering into any bilateral treaties and maintain a balance between IP monopolies of private individuals with public interest.

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[53] *Supra note* no. 45 at. art 12.1.

[54] *Supra note* no. 46