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# TRIPS AGREEMENT: TRADE AND PUBLIC HEALTH TAKE SHOTS ON EACH OTHER

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**ABSTRACT**

*The debate between IP and Human rights particularly, Public Health comes into picture when the concern of access to essential medicines at affordable prices in developing and least developed countries is raised. In this whole deliberation TRIPS Agreement and Doha Declaration has an important role to play. The TRIPS Agreement raises a strong question that whether the Industrial interest shall be kept above public health? Through the DOHA Deceleration it was assured that TRIPS agreement includes various flexibilities like transitional period, compulsory licensing, parallel imports, etc. by which they can tackle their health problems.But in practice, use of the flexibilities provided by the TRIPS agreement was being challenged, politically and legally, by multinational pharmaceutical companies and developed countries. The strategies adopted by the developed countries and pharmaceutical industries can call them an INTELLECTUAL TERRORIST.Here in this article we will discuss the TRIPS Agreement and Doha Declaration in brief and assessed their impact on Public Health*

***Keywords:Human Rights, Public Health, Industrial Interest and Intellectual Terrorist***

## I. INTRODUCTION

It is a silver jubilee for the TRIPS agreement in the year 2020; however, one can get confused about how successful it has been in the last twenty-five years because protests against it started not after its enactment but also before the enactment by the developing and underdeveloped countries during Uruguay Round of GATT. No doubt that the TRIPS agreement contributed significantly to the world of Intellectual Property (IP)but it also affected drastically the Pharmaceutical Sectors when there is a hue and cry for Human Rights (especially- "*right to life, right to health, and right to access medicine").* As the majority of the population in developing and most of the population in underdeveloped countries is living below the poverty line so the prices of the essential medicines which are not affordable for them indicate that there is going to be a health crisis in these countries.

On the other hand, we are familiar with the theory of Intellectual property that why we should have intellectual property, one set of explanations is from the Economic point of view which is based on non-rivalries nature of information or knowledge. That means "information is private goods in production i.e. it costs money and human resources to produce, but once produced it is public goods for consumption".[1] In such a condition it is detrimental to producers who may not get an adequate incentive for their production and ultimately may lead to underproduction of goods. So, the Economic theory is of the view that "…the solution to this public goods problem is intellectual property. By creating a limited monopoly called an intellectual property right, we can give producers an adequate incentive to create".[2]

Now,this brings up the question that it is significant to provide a monopoly for IP aboutthe invention related to health care? Even if we considered *incentive theory* which encourages the inventor or creator for more invention and creation it is not possible to provide some exemption in the pharmaceutical sector, especially for essentials medicines?

[1] Dr. Francis Gurry, 'Rethinking the Role of Intellectual Property'Presentation(Melbourne Law School,22 August 2013)<https://www.youtube.com/watch?v=Z5PIJ-mAtpY&t=673s> accessed 08 May 2020
[2]Mikhalien Du Bois, 'Justificatory Theories for Intellectual Property Viewed through the Constitutional Prism' (2018) 21 Potchefstroom Elec LJ 1

This debate between IP and Human rights particularly, Public Health comes into picture when the concern of access to essential medicines at affordable prices in developing and least developed countries is raised. In this whole deliberation TRIPS Agreement and Doha Declaration has an important role to play. The TRIPS Agreement raises a strong question that whether the Industrial interest shall be kept above public health[3]? Here in part II and part III we will discuss the TRIPS Agreement and Doha Declaration in brief and assessed their impact on Public Health and finally, in part IV, we will discuss findings and concludes.

## II. TRIPS AGREEMENT AND PUBLIC HEALTH

In the late 20th Century, the Generic Companies,especially in developing countries,are at the peak in making a generic version of the patented drugs since there are no uniform international norms for the protection of new pharmaceutical products. Such a practice was strongly opposed by the developed countries, especially by the USA, EU, and Japan.It is the reason that during the Uruguay Round of negotiation Developed Countries werecontinuously putting pressure to provide adequate reward through IP protection to the pharmaceutical companies, who were making a considerable investment for the invention, production, and marketing of essential drugs.[4] As a result,an international norm through TRIPS Agreement was enactedand it is mandatory for all the members of the WTO to sign the TRIPS Agreement. Therefore, developing countries like India and underdeveloped countries mustsign the TRIPS Agreement and accordingly compel to change their existing patent law. For instance, the Indian Patent Act, 1970 which only allows processpatent and not the product patent inthe pharmaceutical sectormust amend the law and have to provide product patent also.

Before the TRIPS Agreement, the obvious reason for the Indian Patent Act that does not provide patent productsis to produce the same pharmaceutical product through a different process and to

[3]Rakesh Mondal, 'TRIPs agreement and public health: Indian experience' (2017) 3(4) International Journal of Applied Research <http://www.allresearchjournal.com/archives/2017/vol3issue4/PartD/3-4-48-111.pdf>accessed 10 May 2020

[4] N S Gopalakrishnan, 'TRIPS Agreement and Public Health: An Overview of International Issues'(2008) 13 Journal of Intellectual Property Rights <https://dyuthi.cusat.ac.in/xmlui/bitstream/handle/purl/4717/TRIPS+Agreement+and+Public+Health+An+Overview+of+International+Issues.pdf;jsessionid=C3BA63467D796E7506E04D264C9EC943?sequence=1>accessed 10 May 2020

facilitate access to essential medicine at an affordable cost to the large section of poor people. However, after the enactment of the TRIPS Agreement, it leads unpleasant situation in all the developing and developed countries that largely depend on the generic drugs since the essential medicines now become expensive and out of reach of the poor patients.

However, atthe same time, it cannot be ignored that the TRIPS Agreement had the potential to create the interest of the pharmaceutical industryin developing those drugs for the diseases that happen exclusively or overwhelmingly in theleast developed countries. This will result in favorof the minority[5] and as after the exclusive period of monopoly gets overthe drugs would be able to reach out tothe people of those underdeveloped countries which as of now are themajor concern as the drugs are not being developed for them.

Further, it was highlighted that TRIPS Agreement provides some flexibility for the developing and underdeveloped countriesconcerning public health viz.- "transition period (to implement their TRIPS obligations), compulsory licensing, public and non-commercial use of patents, parallel importation, exception to patentrights, exemption from patentability and limits on data protection".[6] Thus the impression given to the world is that TRIPS Agreement is very concerned about public health.

However, developing countries had different thoughts intheirminds and are only concern about makingmonetarybenefits out of their patented drugs. For instance, the situation in Thailand was so created by the USA that they are not in positions to use such flexibilities provided by the TRIPS Agreement.There the American Firm Bristor-Myers and Squibb (BMS) sold the drug at $2.5 per tablet in a country where the daily minimum wage averaged $ 3.84.[7] The Government Pharmaceutical Organization (GPO) requested for Compulsory Licensing under the Thai Patent Act and TRIPS agreement.However, under the pressure made bythe US, they surrenderedand put an end to the procedure for the issue of a CL.

[5] Shubhra Khana, 'TRIPS, Pharmaceutical Patents and Health Care for the Poor in India' (2016) ILI Law Review <http://ili.ac.in/pdf/paper5.pdf> accessed 10 May 2020
[6] N Lalitha, 'Doha Declaration and Public Health Issues' (2008) 13 Journal of Intellectual Property Rights <http://nopr.niscair.res.in/bitstream/123456789/2026/1/JIPR%2013(5)%20401-413.pdf> accessed 12 May 2020
[7] ibid

Another situation was created in South Africa when 39 drug companies took the South African government to court to challenge the legislation that sought to use the TRIPS flexibilities.[8] Thus in practice, use of the flexibilities provided by the TRIPS agreement was being challenged,politically and legally, bymultinational pharmaceutical companies and developed countries.[9]In this way,such behavior can call them an ***INTELLECTUAL TERRORIST.***

Further Article 31(f), article 31(h) of the TRIPS agreement was also opposed as it limits the rights ofexporting and importing pharmaceutical products.There is also concern raised by the Developing countries, underdeveloped countries, and health activists that this flexibility of compulsory licensingcannot be utilized by them since they do not have such manufacturing capabilities. All these circumstances lead to re-affirmation of the TRIPS Agreement which finally resultant in the form of the DOHA Declaration.

## III. DOHA DECLARATION

The Doha Declaration, 2001 was considereda great achievement of Developing and underdevelopedcountries as they were success in convincingthe world about the drawback of the TRIPS agreement concerning Public Health. The DOHA Deceleration re-affirmsand reinforced the flexibilities provided by the TRIPS agreement.The deceleration,on one hand,highlighted the gravity of the public health problem and on anotherhand also highlighted the importance of the protection of IP for the development of the new medicines and their impact on the prices of the medicines.[10]

Accordingly,the deceleration mentioned that the TRIPS agreement 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.[11] In this way, the deceleration in Para 5 recognizes the flexibilities in the TRIPS agreement and clarified that each member has the

[8] Policy Brief, 'The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation'South Center (2011) <https://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf> accessed 12 May 2020
[9] ibid
[10]World Trade Organization, 'Declaration on the TRIPs Agreement and Public Health' (Ministerial Conference Fourth Session, Doha, November 2001) <https://www.who.int/medicines/areas/policy/tripshealth.pdf>
[11] ibid

freedom to recognize the grounds of the compulsory license and freedom to determine national emergency or other circumstances of extreme urgency.[12]

Further in Para 6 of the decelerationthey recognize that country-"with insufficient or no manufacturing capacities in the pharmaceutical sectorcould face difficulties in making effective use of compulsory licensing under the TRIPS Agreement"and therefore, they instructed Council-"for TRIPSto find an expeditious solution to this problem".As a result, a draft *Article 31bis* was proposed for the amendment to the TRIPS agreement. This includesthe eligibility of the importing and exporting member toensure that only deserving countries are going to use compulsory licensing. It further waived the limitation on importing and exportingthe pharmaceutical product. The proposed amendment was incorporated in the TRIPS Agreement by the Amendment of the TRIPS Agreement 2005.

Now after incorporation of Article 31bis it was expected to have a high number of compulsory licensing. However, only one country viz. Canada has issued a compulsorylicense under Article 31bis to provide generic AIDS drugs to Rwanda till 2011.[13]The difficulties in using Article 31bis was identified byan author as- it was a complicated process, there is a fear of retaliation, and bilateral agreement has restricted the use of the compulsory licensing.[14]

Further, the transitional period was also extended for the least developing countriesuntil 2016 for pharmaceutical patents and test data protection in compliance with the Para 7 of the Declaration.Concerning the public use, the Declaration extended the use of the patent for the other epidemics where the state can identify local health problems or pandemic and use the patent for the same.

However, the DOHA Declaration in itselfis not a complete explanation for the public health as it does not touchsome of the flexibilities in TRIPS agreements like what exception will be given

[12]ibid
[13]Donald Harris, 'TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing' (2011) 18(2) Journal of Intellectual Property Law <https://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?article=1184&context=jipl> accessed 15 May 2020
[14]ibid

against patent rights andcases where protection of data will be submitted for the registration of pharmaceutical products.

Though the DOHA deceleration is animportant politicaldocument between developed and developing (or least developing countries) it had certain limitations and has not achieved to keep public health more important than trade.

For instance,an author observed that- "the regional and free trade agreements (R&FTA) signed between the developing and the developed countries introduce TRIPS-plus provisions which impede access to medicines."[15]Thus these regional agreementscreate restrictions to get access to medicines and become more powerful than the multilateral agreements.[16]

## IV. CONCLUSION AND FINDINGS

As we had seenthat developed and developing (incl. underdeveloped) countries are at war with each other during the Uruguay Round of GATT. Where the developed countries argued that there is a call for international norms for the protection of new pharmaceutical products.On the other hand, developing and underdeveloped countries oppose the proposal in the light of public health policies (i.e. access to medicines at an affordable cost). As a result,a developed country, especially, the US uses political and legal strategies to dominate developing and underdeveloped countries, for example, Thailand and South Africa cases disused above.Finally, the developed countries won the battle, and their proposal wasaccepted and formulated into a document called TRIPS Agreement where all the WTO members are obliged to sign the agreement including developing and underdeveloped countries. Such a mandatory obligation is likeagain colonizing developing and underdeveloped countries by the developed country in the name of Globalization, Westernization, and Industrialization.They were assured that agreement includes various flexibilities like transitional period, compulsory licensing, parallel imports, etc. by which they can tackle their health problems.

[15] n 7
[16] ibid

However, again the developing and underdeveloped countriesoppose the agreement when they realize that the flexibilities which are provided to them had more restrictions than freedom. This leads to re-affirmation of the TRIPS Agreement which finally resultant in the form of the DOHA Declaration.

If we analyze the above-mentioned points in Part II, we can conclude that position before the TRIPS agreements were more favorable to the developing and developed countries as the accessibility and availability of medicines at affordable prices was not aproblem for them.One can always question the step taken by WTO to include intellectual property protection in their trade domain when it is more important to help socially and economically underdeveloped countries. The intellectual property protection and TRIPS rather striking balance between developed countries anddeveloping counties (incl. underdeveloped countries) again demarcated line between these countries.

However, on the other hand, one cannot alsodeny the fact that this TRIPS agreement and incentive theory encourages pharmaceuticalsindustry to invest more for R&D and invent new and more effective drugs for the diseases which were declared to be pandemic from time to time like HIV/AIDS, TB, etc. and now the COVID-19. If we think from another perspectivewe can realize that if the TRIPS agreement did not restrict these generic drugs manufacturer companies from making ageneric version of patented drugs,there will be no incentive for the patent holder,whichleads to no further invention and no new medicines will be available which is also detrimental to the right to health and access to medicine.If we analyze the above-mentioned points in PartIII, we can conclude that Doha deceleration is only a trap to dominate the voices raised against the TRIPS Agreement by the Developing and Developed Countries. This statement can be supported by the fact thatthe Doha Declaration focuses on the genuine and critical problems experiencedby many developing and underdeveloped countries in the area of public health but it doesnot intend to amend the TRIPS Agreement in any substantial manner.[17]On the contrary, it only aims to highlight how the TRIPS Agreement concerned about

[17]Carlos M. Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health' (University of Buenos Aires, June 2002)<https://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf> accessed 15 May 2020

public health policies andhighlighted the right and flexibilities available to the member state under the TRIPS agreement.Thus, we can conclude that the incentive theory incorporated in the TRIPS Agreement was more dominating over the public health problems.Secondly, the Doha Declaration represents, rather than the end of a process, the initial step for rethinking the TRIPS Agreement considering the public interest.[18]The strategies adopted by the developed countries and pharmaceuticalindustriescan call them an ***INTELLECTUAL TERRORIST.***Developed countries should accept the responsibility and not treat their monetary policies more important than public health and co-operate with the developing countries(inc. underdeveloped countries)to secureand promote general health.So overall discussion can be concluded as it is time to re-think the TRIPS Agreement not only from the public health aspect but including but not limited to international tradeand intellectual property aspect as well.

[18] ibid