ISSN 2582 - 211X

LEX RESEARCH HUB JOURNAL

On Law & Multidiciplinary Issues

Email - journal@lexresearchhub.com

VOLUME II, ISSUE I
OCTOBER, 2020

https://journal.lexresearchhub.com

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AN INSIGHT INTO THE IMPACT OF 30 AUGUST 2003 DECISION OF WTO ON TRIPS AGREEMENT & PUBLIC HEALTH

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2018-2019 LL.M

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ABSTRACT:

This article firmly presents an investigation into the 30 August 2003 decision of WTO concerning the implementation of Paragraph 6 of Doha Declaration on the TRIPS Agreement and public health; thereby revealing the underlying issues and conditions that are directly and indirectly affecting the access to public health systems and medicines in the developing countries. The article prominently highlights the issues concerning the compulsory licensing procedures, patent term extension, implications of data exclusivity, patent linkage and the barriers related to the imposition of the TRIPS flexibilities. It explains their global effect on the contemporary public health system. The article critically points out the possible causes behind the underutilisation of Paragraph 6 system. It suggests the means and tools for improving and facilitating the access to medicines by the developing countries to retain the objectives of the much-discussed Paragraph. An assessment into the impact of the available flexibilities provided in the TRIPS and their limitations, aptly portrayed the suggestive measures that are required to comply with the real sense of the TRIPS, thereby promoting and ensuring global access to the public health and medical system. This article aims to spotlight the hurdles and loopholes both at the national and international level that prevents the implementation of mechanisms needed to promote access to medicines and public health mechanisms for the developing countries. The undermining causes and the remedies needed to resolve the operability of Paragraph 6 in compliance with the TRIPS, has been meticulously explained in the article.

INTRODUCTION:

"You cannot achieve environmental security and human development without addressing the basic issues of health and nutrition"- Gro Harlem Brundtland[1]

The Director-General of the World Health Organisation (WHO) from 1998 till 2003, Gro Harlem Brundtland, aptly pointed out the actual need of the nation in order to attain sustainable

[1] Gro Harlem Brundtland Quote: https://quotefancy.com/quote/759596/Gro-Harlem-Brundtland-You-cannot-achieve-environmental-security-and-human-development.

development.[2] However, it is indeed hard to define an ideal health development system based on the aspects of political and economic agendas of a particular country. Nevertheless, a rough structure, almost tending towards idealism could be presented when it comes to the mechanisms of the health development system. The construction of such a rough structure will be possible only with the availability of equitable access towards protecting public health.

A revolutionary change was expected on such access towards public health when the decision made by WTO (World Trade Organization) on 30 August 2003 on the implementation of "Paragraph 6 of the Doha Declaration on the TRIPS (Trade-Related Aspects of Intellectual Property Rights)" Agreement & Public Health came into form.[3] Considering the needs of eligible importing members of WTO, it was required to find a quick solution related to the problem that the WTO members with no manufacturing or insufficient capacities in the pharmaceutical sector can encounter in making effective use of compulsory license under the TRIPS Agreement.[4] The requirement for a prompt solution to the problem of compulsory license was mentioned already at the 4th WTO ministerial conference of Doha on 14 November 2001.[5] Earlier, existing provisions of the TRIPS granted the compulsory license in order to permit the generic production of medicines. However, this flexibility was not available to countries lacking in domestic manufacturing capacity.

The restrictions in the TRIPS Agreement immensely hampered the import of generic medicines which required that under a compulsory license, the production needs to be mainly for the supply to the local market. Consequently, the concern raised in this matter was that the exporting countries might have problems while exporting the required amount of medicines which can meet the other countries requirements having low manufacturing or insufficient capacity. Paragraph 6 of the Doha Declaration recognised this problem and after two years of negotiations, came out with a practical

[2] Agitha, T. G. "TRIPS Agreement and Public Health: The Post Doha Crises." (2013).
[3] WHO | Medicine procurement and the use of flexibilities in .... https://www.who.int/bulletin/volumes/96/3/17-199364-ab/en/.
[4] Danovitch, Gabriel M., Jeremy Chapman, Alexander M. Capron, Adeera Levin, Mario Abbud-Filho, Mustafa Al Mousawi, William Bennett et al. "Organ trafficking and transplant tourism: the role of global professional ethical standards—the 2008 Declaration of Istanbul." Transplantation95, no. 11 (2013): 1306-1312.
[5] Chow, Daniel CK, and Edward Lee. International Intellectual Property: Problems, Cases, and Materials. West, 2012.

solution to this problem in the year 2002.[6] This solution was a waiver of the export restriction, which then allowed the exportation of the total production of pharmaceutical products under a compulsory license.[7]

II. DETAILED ANALYSIS OF PARAGRAPH 4:

The flexibilities provided in the TRIPS are affirmed by Paragraph 4 of the Doha Declaration, which states that the TRIPS does not prevent members from taking any measures which are required to secure the public health. Also, there arose a requirement for the interpretation as well as the implementation of the Agreement that conforms to the rights of WTO members, in order to secure the public health as well as to encourage access to medicines for all.

Developing countries were actually in search of a declaration which could recognise their rights to implement specific measures with which they can compete; such as compulsory license and parallel imports necessary to improve admittance to the health care system.[8] These emerging countries became stressed due to the pressure and opposition exerted by the pharmaceutical industries and governments to implement patent legislation that goes beyond the obligation of the TRIPS, referred to as "TRIPS-plus."[9] TRIPS-plus is an effort to extend patent life beyond the 20 years limitation in order to tighten the patent protection and limit the compulsory licensing which in turn would restrict the exceptions that are responsible for facilitating the quick introduction of generic medicines.

A leading issue that comes in the discussion of Paragraph 4 is that up to what extent the concluding provision of Article 8.1 of the TRIPS would mean that IP can dominate the public health.[10] The

[6] Danovitch, Gabriel M., and Mustafa Al-Mousawi. "The Declaration of Istanbul—early impact and future potential." Nature Reviews Nephrology 8, no. 6 (2012): 358.
[7] Ezeani, Elimma. "WTO post Doha: trade deadlocks and protectionism." Journal of International Trade Law and Policy12, no. 3 (2013): 272-288.
[8] Lee, Donna. "Global trade governance and the challenges of African activism in the doha development agenda negotiations." Global Society 26, no. 1 (2012): 83-101.
[9] Kilic, Burcu. "Defending the Spirit of the Doha Declaration in Free Trade Agreements: Trans-Pacific Partnership and Access to Affordable Medicines." Loy. U. Chi. Int'l L. Rev. 12 (2014): 23.
[10] Owoeye, Olasupo Ayodeji. "Compulsory patent licensing and local drug manufacturing capacity in Africa." Bulletin of the World Health Organization 92 (2014): 214-219.

interpretation of Article 8.1 under the light of Paragraph 4 states that Article 8.1 does not prevent any derogation under the TRIPS when it is required to resolve any needs related to public health.[11]

Paragraph 4 not only highlights the interpretation of the Agreement but also on its mandatory implementation which states that one member country should not restrain other member countries from interpreting and implementing the Agreement responsive to their rights, in order to secure the public health. In interpreting the second part of Paragraph 4 of the Doha declaration, we get the mention of several flexibilities conferred by the TRIPS.[12]

III. FLEXIBILITIES BY THE TRIPS:

Spelling out the concept of flexibilities provided in the TRIPS Agreement is one of the core aims of the Declaration. These flexibilities are subject to several legal and political implications at the national level.[13] "Article 6 of the TRIPS Agreement" when cited in contrast to the Paragraph 5(d) of the Doha Declaration, suggests that the freedom to choose the individual exhaustion regime of the intellectual property rights should be left free to be decided by each member without any challenge that is subject to the provisions of Most Favoured Nation and National Treatment as enumerated in Article 4 and Article 3 of the TRIPS.[14] Paragraph 5 (d) of Doha declaration when read with Paragraph 4, exclusively clears the fact that the only goal of the Declaration is to protect public health.

IV. IMPLICATIONS OF DATA EXCLUSIVITY:

The other aspect of Doha Declaration on health which may have a significant impact in the interpretation of the TRIPS Agreement is that paragraph 5(d) does not apply only to Article 6 but rather to all the provisions of the TRIPS that deals with the exhaustion of IPR. The relationship

[11] Lester, Simon. "Is the Doha Round Over? The WTO's Negotiating Agenda for 2016 and Beyond." The WTO's Negotiating Agenda for (2016).
[12] Lee, Donna. "Global trade governance and the challenges of African activism in the doha development agenda negotiations." Global Society 26, no. 1 (2012): 83-101.
[13] Lee, Donna. "Global trade governance and the challenges of African activism in the doha development agenda negotiations." Global Society 26, no. 1 (2012): 83-101.
[14] Hartman, Stephen W. "The WTO, the Doha Round Impasse, PTAs, and FTAs/RTAs." The International Trade Journal 27, no. 5 (2013): 411-430.

between Article 39.3 and Article 6 is quite direct. Article 39.3 deals with the fortification of undisclosed test or other data that are hard to procure and submit to the governments in order to get an endorsement for the marketing of the agricultural or pharmaceutical chemical products which uses new chemical entities.[15]

The TRIPS Agreement requires the WHO (World Health Organization) members to protect confidential data on pharmaceutical products against unfair competition. Thereby, the members are barred from granting any exclusive rights over data, as is done under the sui generis system in the USA and EU.[16] The FTAs (Free Trade Agreements) negotiated by the USA deviates from the TRIPS standard. It obliges the parties to grant exclusive rights for at least five years whether the products are patented or not and whether the data are undisclosed or not. Such exclusivity will apply even if the national health authority requires the submission of the data or not and covers chemical entities that are not "new."[17]

V. PATENT TERM EXTENSION:

Under Article 33 of the TRIPS, the patent protection term is 20 years. Several LDCs (Least Developed Countries) have agreed to adjust the term of the patent for "unreasonable" delays in the issuance of the patent, which is "more than five years from the date of filing of the patent application." Patent protection term extension could also be one of the reasons for the delay caused in granting marketing approval for a drug.

However, the patent term adjustment provision comes with several other implications. Firstly, it would enable the right holders to impede the launch of the product in relatively low-priced markets. Secondly, to delay the launch and to portray the inefficiency of the approval procedure, the innovators could even provide incomplete data to the drug regulators. Thirdly, it could finally deny access to a new drug in the lower-priced markets. Fourthly, even after the expiry of the product's

[15] Beall, Reed, and Randall Kuhn. "Trends in compulsory licensing of pharmaceuticals since the Doha Declaration: a database analysis." PLoS medicine 9, no. 1 (2012): e1001154.
[16] Feature Article TRIPS. http://nopr.niscair.res.in/bitstream/123456789/12623/1/SR%2048%289%29%2023-25.pdf.
[17] Lee, Donna. "Global trade governance and the challenges of African activism in the doha development agenda negotiations." Global Society 26, no. 1 (2012): 83-101.

patent term in the developed countries, the product could retain monopoly status in the developing countries. It could on an average give at least two years of extended monopoly, further impacting the access to medicines system.

VI. PATENT LINKAGE:

The term "patent linkage" means to connect the drug regulator's marketing approval to the patent status of the drug. The US's Orange Book system provides a 30-month time frame to the drug regulators for approving a generic drug. This approval could effectively lead to three to four years of additional monopoly in other markets, as they do not have Orange Book system, which binds the drug regulator to approve a generic product within the stipulated time frame. Such an absence of a restricted time limit is benefiting the innovators, thus delaying into the launch of generics and depriving the patients of access to affordable drugs.

VII. HIGHLIGHTED FLEXIBILITIES:

Article 8 vividly defines the principles of the TRIPS Agreement, which suggest that the TRIPS member while amending or formulating their regulations and laws might accept measures which are consistent with the provisions of the agreement. Also will be required to secure public health and nutrition in order to endorse the public interest in the required fields necessary for socio-economic as well as development in technology.[18] The second part of Article 8 suggests that the apt measures which are required to be adopted to stop the misuse of rights relating to IPR by the right holders or the need to resort to practices which develops pointless trade barriers by impacting the free flow of trade and other international transference of technology and must be consistent with the provisions of the TRIPS Agreement [19] . However, Article 27 (2) authorises members to restrict the acknowledgement of patents if the inventions are dangerous for human life and to public health.

[28] Bashar Malkawi, 'David A. Gantz: Liberalizing International Trade After Doha: Multilateral, Plurilateral, Regional, And Unilateral Initiatives' (2015) 8 Law and Development Review.
[19] Chow, Daniel CK, and Edward Lee. International Intellectual Property: Problems, Cases, and Materials. West, 2012.

The additional flexibilities under the Paragraph 6 system are not mandatory somewhat optional. Hence, in order to take advantage of those flexibilities, several WTO members have incorporated the Paragraph 6 system into their respective domestic legal frameworks. There are WTO Members that have implemented Paragraph 6 exclusively as exporters. Whereas, some members agreed to act exclusively as importers. Also, some members have agreed to act as importers only in situations of national emergency or other circumstances of extreme urgency.

The problem of access to essential medicines faced by countries like Asia and Africa, with almost 50% of the population, the reasons being two-fold. Firstly, the capacity of the LMICs (Low Middle-Income Countries) to implement the flexibilities provided in the TRIPS gets stuck amidst inequalities in health resources and the world trading system as a whole. Secondly, the flexibilities get undermined by provisions adopted in several bilateral and regional trade agreements. The standard of IPRs that are being adopted or negotiated in TRIPS-plus or under other trade agreements is more restrictive to the public health protections. These two concerns have led to increased tensions between the public health and trade policy communities, which are creating hindrance in accessing the flexibilities mentioned above.[20]

VIII. ISSUES IN COMPULSORY LICENSING:

A compulsory license is a legal grant whereby a government grants to itself or a third party, the right to produce or to import a patented product without the authorisation of the patent holder. Article 31 of the TRIPS does not expressly define compulsory license instead refers to ‘other use’ which again denotes the uses other than those permitted under Article 30.[21] Article 31 also states ‘use without authorisation’ which further explains that a compulsory license granted through competent national authority in order to permit that competent state authority or other vendors to develop an original product without the approval of right holder. In this context, preference is

[20] Kilic, Burcu. "Defending the Spirit of the Doha Declaration in Free Trade Agreements: Trans-Pacific Partnership and Access to Affordable Medicines." Loy. U. Chi. Int'l L. Rev. 12 (2014): 23.
[21] Chow, Daniel CK, and Edward Lee. International Intellectual Property: Problems, Cases, and Materials. West, 2012.

given much to the public interest in order to achieve the target of access to the patented invention rather than the private interest of the right holder.[22]

The European Commission (EC) proposed a flexible interpretation of Article 30 to make the ease implementation of Paragraph 6. Some of the countries have supported it, but the USA rejected such a proposal. The EC proposed that the limited exceptions under Article 30 could be interpreted to allow for the export of pharmaceutical products to countries lacking in manufacturing capacity. However, the US rejected such a proposal on the ground that it might prejudice the rights of members under the TRIPS. It was not probable that any exceptional interpretation of Article 30 could be possible without implying the grant of compulsory license since the generic manufacturers would not feel encouraged to invest in reverse engineering of a patented product to export it in small quantity with a low profit unless there is any severe crisis in any poor LDC. Hence, a compulsory license was necessary to resolve this issue.

However, the Paragraph 6 system under the 2003 decision offers three derogations from obligations addressed under Article 31. The first derogation states that under Article 31(f), the obligation of the exporting members to issue a compulsory license for the domestic market does not apply to the extent necessary to enable such exporting member to authorise the productions and export of the needed pharmaceutical products under a compulsory license to those member countries that lack sufficient manufacturing or production capacity. This derogation is meant to provide a transparent operation of Paragraph 6 system, where the countries genuinely lacking in such domestic production or manufacturing capacity or are in real need can import under it. The derogation also protects trade diversion and ensures the right supply of products to the markets for which they are genuinely intended.[23]

The second derogation suggests that under Article 31 (h) if a compulsory license is granted to both the exporting and importing countries, then payment needs to be paid only to the countries who

[22] Agitha, T. G. "TRIPS Agreement and Public Health: The Post Doha Crises." (2013).
[23] Lester, Simon. "Is the Doha Round Over? The WTO's Negotiating Agenda for 2016 and Beyond." The WTO's Negotiating Agenda for (2016).

export.[24] This derogation is to avoid double remuneration to the right holder. The third derogation which comes under Article 31 (f) suggests that a member of WTO can export products, manufactured or imported under a compulsory license easily between the members under Regional Trade Agreements where half of the members are from LDCs.

Under Article 31(b) the provision for the requirement to negotiate with the right holder on reasonable commercial terms and adequate remuneration could be waived in circumstances of extreme urgency which the member states are free to define terms on their own.

Under the transitional arrangements of the TRIPS, the developing countries could buy generic drugs from a few producers like India. However, they are powerless to do so after 1 January 2005. Under the transitional arrangements, addressed under Article 65(4) the developed countries are needed to enlarge their patent protection in the technological area, not secured within the specific date of application of the TRIPS Agreement. Since 2005, a member of WTO affected by any public health crisis will be incapable of importing generic products from another member who comes under compulsory licensing condition until the other country has invoked an equivalent license.[25]

However, the provisions of Article 31(b) and Article 31 (f) will not apply where the compulsory license has been permitted to remedy any anti-competitive practice as determined by a judicial or administrative body. As addressed under Article 31(k), while determining the remuneration of the right holder, the need to remedy such practice should come under consideration. Also, the contracting parties may limit the right holder's exclusive right solely through a compulsory license in order to remedy an adjudicated violation of anti-trust law.

[24] Nicol, Dianne, and Olasupo Owoeye. "Using TRIPS flexibilities to facilitate access to medicines." Bulletin of the World Health Organization 91 (2013): 533-539.
[25] Lee, Stacey B. "Can Incentives to Generic Manufacturers Save the Doha Declaration's Paragraph 6." Geo. J. Int'l L. 44 (2012): 1387.

IX. REASONS SUPPORTIVE TO THE FAILURE OF PARAGRAPH 6 IN IMPROVING ACCESS TO MEDICINES:

Undoubtedly, the role of the pharmaceutical companies in discovering and developing effective drugs plays a significant role in access to effective medicines system. However, it is also not immune to setbacks. The industry is getting trumped due to the patent rights expiration on highly profitable products, fierce competition through the generics, failure in growing new group of drugs as well as other public criticisms.[26] The goal of securing access to medicines has somewhere got trampled between the public interest and profit-making targets.

"Paragraph 8" of the 2003 Decision states that the "Council of TRIPS" needs to review the operability of Paragraph 6 system annually in order to ensure operations are effective. Since 2004 a regular report to the General Council had been prepared annually.[27] Derogation to this practice took place in October 2009. Debates arose subject to any replacements concerning the utilization of the Paragraph 6 system to achieve the objectives of access to medicines and other related policies. In the course of such discussions, some member countries raised concerns relating to the functioning of the Paragraph 6 system which they found to be too much complex and bureaucratic and did not meet the expectation in resolving the public health problems faced by the developed countries. According to these member countries, the inadequacy of Paragraph 6 system could be because of its limited use and little acceptance by the member countries.

The objectives and purpose of the flexibility of Paragraph 6 were to offer a speedy solution to the complexities of the affordable availability of medicines, particularly at the time of emergency.[28] This flexibility application is quite tiresome and unnecessarily onerous. Although, the utilisation of flexibility includes many formalities which in turn develops an administrative burden on both the importing and the exporting countries. This utilisation of flexibility needs to make specific

[26] Liu, Jodie. "Compulsory Licensing and Anti-Evergreening: interpreting the TRIPS flexibilities in sections 84 and 3 (d) of the Indian Patents Act." Harv. Int'l LJ 56 (2015): 207.
[27] Frankel, Susy. "The intellectual property chapter in the TPP." The trans-Pacific partnership: a quest for a twenty-first century trade agreement. Cambridge University Press, Cambridge (2012): 157-170.
[28] Abbott, Frederick M. "The cycle of action and reaction: Developments and trends in intellectual property and health." In Negotiating Health, pp. 43-56. Routledge, 2012.

changes to national patent laws because the achievement of objectives through this flexibility is dependent on the will of the member states to enact the same into their domestic legislation. Most of the LMICs have failed to include this complicated waiver flexibility in the local patent laws. The device remained unutilised, which practically failed to solve the problems.[29]

Incorporation of TRIPS-plus measures in the FTAs and lack of technical assistance as addressed under Article 67 of the TRIPS plays a significant role in creating a barrier towards the access to the medical system. Technical assistance like preparation of laws and regulations required for protection and enforcement of IPR, the establishment of reinforcement agencies related to health issues, including training personnel who would assist countries in becoming TRIPS compliant. Lack of such technical assistance became a threat to the smooth use of flexibilities provided in the TRIPS. Also, promotion of TRIPS-plus measures like the extension of patent term, the introduction of data exclusivity, patent linkage with drug registration and approval through the FTAs are further undermining the spirit of Paragraph 6 of Doha.

Another crucial issue is that Paragraph 6 and the Doha Declaration remained silent concerning the underinvestment issue in Research and Development (R&D) for health conditions that chiefly impacts the LMICs. These R&Ds remains more concentrated in a small number of large pharmaceutical companies that serves high-income country markets. For instance, there are more drugs for brain tumours than for tuberculosis which is one of the globally killer diseases, especially in the developing world. Why? The reason is that the R&Ds are more inclined towards profit-making financial concerns which promise the most significant economic return rather than the genuine public health concerns.[30] Hence, most LMICs lacking in domestic R&D, could not meet the significant health needs. Thus, the objectives of Paragraph 6 remains defeated.

[29] Leudjou, Roland Njiteu. "The Doha Round and Food Security in the Dairy Sector in Cameroon: A Global Simulation Model (GSIM) Approach." Estey Centre Journal of International Law & Trade Policy 13, no. 1 (2012).
[30] Wolfe, Robert. “First diagnose, then treat: what ails the Doha Round?.” *World Trade Review* 14, no. 1 (2015): 7-28

X. CONCLUSION:

The Doha Declaration claims the need for the implementation of the Agreement in both national and international level. There should be a more comprehensive approach towards securing access to medicines like research and development of new drug policies and funding policies. Other policies may include effective competition policies with proper competitive, transparent and non-discriminatory procurement practices and procedures. These practices are required to affirm the safety, quality, and efficacy of the medicines; must abolish tariffs and sales taxes; must implement an adequate health care infrastructure. Alternative funding mechanisms like partnership programmes, donations, and other licensing agreements, as well as applications by the pharmaceutical companies for tiered pricing programmes, have always contributed towards an increased improvement in securing access to medicines.[31] The lack of progress in implementing the TRIPS flexibilities to improve access to medicines and the spread of TRIPS-plus measures through bilateral and regional trade agreements requires special attention. For achieving public health and access to affordable medicines, it is required to implement the objectives of Paragraph 6. Besides, bringing improvement in public health care systems, awareness via education programmes, introducing new research into treatments for diseases that are affecting the developing countries, contributing to Global Funds and also the actions of corporate donors and public-private partnerships will add into the action of retaining the true spirit of Paragraph 6 system in the long term.

[31] Abbas, Muhammad Zaheer. "Pros and cons of compulsory licensing: An analysis of arguments." International Journal of Social Science and Humanity 3, no. 3 (2013).