Paragraph 6 System: is it Viable?

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a. Introduction

Fundamentally, according to World Health organisation, one of its main goals is to react to health issues in a holistic manner.[1] In the many factors that have a huge bearing in the delivery of health, the provision of drugs remains one of the crucial elements. Equally, it is the fundamental human right to receive proper medical care, and that cannot be possible if the medical drugs are not included.[2] Realistically, medical drugs are expensive to make as they consume a considerable amount of resources from research to actual production to its state that can be administered to patients. Due to the astronomical costs involved in the production and the need for pharmaceuticals manufacturer's to recoup and protect their investments through patenting, the cost and accessibility of medical drugs have become a serious challenge in both developing and least developed countries (LDC).

Thereupon, the Paragraph 6 System was deliberately formulated to strike a balance between protections of intellectual property rights (IPR) while guaranteeing affordability and accessibility of medical drugs mainly through compulsory licensing.[3] Although, it was well intended, Paragraph 6 System has not achieved much in ensuring accessibility of these essential medicines. Firstly, there are serious problems afflicting developing and LDCs in implementing Paragraph 6 System. Secondly, the system requires complex procedures to implement. Thirdly, actual implementation of the compulsory licensing has also proven to be unmanageable. Fourthly, there are special challenges in accessibility of drugs that treat and manage chronic diseases. There, is vagueness in interpretation and implementation. Moreover, developing and LDC have to contend with retaliations from both pharmaceuticals

[1] World Health Organization, 'Health Promotion' (WHO, 2017) http://www.who.int/healthpromotion/about/goals/en/ accessed 26th March 2017
[2] Article 25 of Universal Declaration of Human Rights 1948
[3] Antony Taubman, Hannu Wager and Jayashree Watal (eds), *A Handbook on the WTO TRIPS Agreement* (Cambridge University Press, 2012) 192

and developed countries. Finally, there are expected legal difficulties in invoking 'Paragraph 6 system.'[4]

b. Problems afflicting developing and LDCs in implementing Paragraph 6 System

In order to conform to World Trade Organization Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities anticipated by 'Paragraph 6 system 'the country intending to use this provision must develop adequate expertise to take advantage of the system.[5] Not only do the users of the system require the technical know-how, but also legal sophistication and intergovernmental coordination must be above par. Realistically, these prerequisites are rare to find in developing and least developed countries.[6] Unfortunately, it is the middle-income countries such as Brazil and India who have pounced on this opportunity while the developing and least developed countries have been left wallowing in the miasma of technical deficiencies.[7]

Uniquely, developing and least developed countries are often ill-equipped to conduct the right disease diagnosis capabilities. This position greatly undermines the ability of these countries to request for adequate quantities and types of medical drugs under compulsory licensing. In most cases, these countries order fewer drugs and when the demand fails to match the supply a crisis is developed, a crisis that Paragraph 6 System intended to forestall.[8]

Unfortunately, some developing and least developed governments or through their agents engage in some unscrupulous dealings. Some of them prefer to resell these medical

[4] Dina Halajian, 'Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem,' [2015] 38:3 *Brooklyn Journal of International Law* 1191, 1202
[5] Fredrick Abbott, 'The future of IPRs in the multilateral Trading System' in Christophe Bellmann and Ricardo Melendez-Ortiz, *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability* (Routledge, 2013) chapter 3 para 2
[6] Ibid
[7] Elizabeth Siew-Kuan, Global Health and Development: Patents and Public Interest in Thomas Pogge, Matthew Rimmer and Kim Rubenstein, *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge University Press, 2010) 104
[8] Ibid

drugs at higher price instead of making them accessible and affordable to their citizens.[9] Conflict of interest and pressure from lobbying may result in misuse of the compulsory licensing provision. For instance, an interesting case occurred in Egypt where the Chairman of the Health Committee in the Egyptian Upper House was also the chairman of generic drug manufacturing company. This conflict of interest was directly evident in the issuing of compulsory licensing of the Viagra drug.[10]

Persistently, developing and least developed countries have faced criticism for their skewed spending habits. Comparatively, these governments have been guilty of channelling vast amounts of resources in military expenditure which is far more expensive but not urgently needed by their citizens. Additionally, unfavourable priority spending increases discontent which spark conflicts necessitating these administrations to procure more arms instead of medicines in the hope of quashing these dissent. Unless, there is a radical reorientation of public spending priorities by these governments especially on building their technical capacity in the medical administration, 'Paragraph 6 System' will not achieve its desired effects.[11]

Notably, the vast majority of citizens in developing and least developed countries have a low purchasing power as most of them are grappling with provision of basic necessities such as food. Most of them when confronted with a difficult choice of whether to purchase food or medication, food will be given a higher preference.[12]

[9] Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (Oxford University Press, 2011) 269-270
[10] Dina Halajian, 'Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem,' [2015] 38:3 *Brooklyn Journal of International Law* 1191, 1212-1213
[11] Adam Wagstaff, Mariam Claeson, Robert Hecht, Pablo Gottret and Qiu Fang, 'Millennium Development Goals for Health: What will it take to Accelerate Progress?' in Dean Jamison et al (eds.) *Disease Control Priorities in Developing Countries* (World Bank Publications, 2006) 184-186
[12] Stuart Schweitzer, Pharmaceutical Economics and Policy (Oxford University Press, 2007) 167

c. Complex procedures to implement 'Paragraph 6 System'

Unfortunately, compulsory licensing is not a straightforward process. Generally, it necessitates overcoming a series of legal, administrative and technical challenges before one can be issued a compulsory license. Even after successful issuance of a compulsory license other related procedures prevent meaningful implementation of Paragraph 6 system. Fundamentally, there are delays in the authorization of these compulsory licenses occasioned by the mandatory legal procedure referred to as judicial reviews or its equivalent. These mundane legal procedures are directly responsible for the deprivation of confidence of the licensees from producing generic versions.[13]

Comparatively, since the pharmaceutical industries are primarily motivated by economic factors, the notion that procedural requirements will inhibit profitability is enough to pour cold water to potential licensees who may intend to deploy this process in anticipation of manufacturing generic medical drugs. Firstly, the process of obtaining a compulsory license is terribly an inefficient method which is resource intensive in terms of time and other pecuniary expenses. Secondly this process mainly exists on paper as its scope of use is few and far between. Thirdly, most jurisdictions do not have an enabling domestic legislation to actualize 'Paragraph 6 system.' Thus this procedure only exists in theory while its practicality has not been sufficiently discerned. For instance, Canada was the first and one of the few countries, to apply 'Paragraph 6 system' as an exporting country of generic antiretroviral drugs to Rwanda. Due to the high consumption of resources because of inefficiency of the process the pharmaceutical company involved vowed not to use the process ever again. Notably, problems in recovering costs, massive initial investments and paltry incentives were cited as major reasons for pharmaceutical industries not being enthusiastic to invest on

[13] Monirul Azam, *Intellectual Property and Public Health in the Developing World* (Open Book Publishers, 2016) 4.2.7

'Paragraph 6 system' let alone attempt to use it. Importantly, some of the pharmaceutical industries have called for world trade organisation to further reform 'Paragraph 6 system' in order to have a meaningful influence and to achieve its desired goal.[14]

d. Unmanageable implementation of the compulsory licensing

As noted above, very few countries have taken advantage of these flexibilities underlined under TRIPS. To put this situation in perspective less than sixty countries have issued compulsory licences. The Doha Declaration was triggered by a reactionary process when South Africa attempted to provide affordable antiretroviral medication in order to manage the HIV/AIDS scourge that was ravaging the population. It was forecasted that after the Doha Declaration there will be an upsurge of this process. However the contrary is true depiction of what have become of the promising declaration.[15]

Regrettably, the process has been used to achieve some other objectives that were not intended by the Doha Declaration. A case point is Brazil which attempted to use compulsory licensing as a conduit to improve its negotiating power in a bid to lower the price of medical drugs. Nevertheless, this process can only be effective when actually implemented but can never achieve the same kind of results if they are used as negotiating tool to reduce prices.[16]

Since compulsory licensing has not been used effectively and in a broad spectrum, its desired objective of reducing the cost of medical drugs has not been significantly achieved. This has had direct and negative repercussions in the access of these vital drugs especially in developing and least developing countries. Medical drugs do have a limited lifespan before

[14] Burton Ong, 'Compulsory licences of pharmaceutical patents to remedy Anti-competitive practices under article 31(k) of the TRIPS agreement: Can competition law facilitate access to Essential medicines?' In Reto Hilty and Kung-Chung Liu (eds.), *Compulsory Licensing: Practical Experiences and Ways Forward* (Springer, 2014) 247

[15] Phoebe Li, *Health Technologies and International Intellectual Property Law: A Precautionary Approach* (Routledge, 2013) 16-18

[16] Luz Bernal, 'Requesting a compulsory licence for Keletra, an HIV/AIDS antiretroviral drug in Colombia' in Abraar Karan and Geeta Sodhi (eds.), *Protecting the Health of the Poor: Social Movements in the South* (Zed Books Ltd., 2015) 18

they can be rendered ineffective. Therefore, newly manufactured drugs that are actually effective come with a price tag that is six times pricier than its older and less effective counterpart.[17]

In instances where compulsory licensing has been granted for the manufacture of generic medical drugs, TRIPS often caps generic manufacturers to only limit themselves to predetermined quantities as strictly stipulated by the compulsory license. This position greatly contravenes the principle of economy of scale where the cost of the end product is determined by the quantity produced. Thus, increased quantity lowers the price.[18]

Complaints have also surfaced that the pricing of drugs after compulsory licensing is unjustifiable as there is negligible price reduction and therefore the intrusion of patents does not push the price down. Forthwith, critics have argued that cost of drugs can only be influenced by market forces such as competition. In addition, *uberrimae fidei* negotiations between genetic drug manufacturers and large pharmaceutical companies who own these patents are a more viable way of reducing prices of medical drugs.[19]

It must be noted that compulsory licensing has been used when there is a looming pandemic therefore its applicability has been used sparingly. Moreover hard questions are also been asked if compulsory licensing has been effective even when it has been used. Anecdotal research shows high mortality rates of the medication in poverty stricken areas where such medicines have been made available through compulsory licensing. For instance,

[17] Jakkrit Kuanpoth, *Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future* (Edward Elgar Publishing, 2010) 32-34
[18] Martin Senftleben, 'Overprotection and Protection Overlaps in Intellectual Property Law- the Need For Horizontal Fair Use Defences' in Annette Kur and Vytautas Mizaras (eds.), *The Structure of Intellectual Property Law: Can one size fit all?* (Edward Elgar Publishing, 2011) 160
[19] N. S. Sreenivasulu, *Biotechnology and Patent Law: Patenting Living Beings* (Manupatra, 2008) 187-188

sub-Saharan African countries still record high mortality rates in preventable and curable diseases such as malaria and tuberculosis.[20]

e. Challenges regarding accessibility of drugs that treat and manage chronic diseases

Currently, chronic and non-communicable diseases are steadily and systematically occupying the deadly pedestal. Statistics also depict that these non-infectious ailments are also responsible for a significant number of patients' fatalities. In light of this development there has been an increase in calls to include medical drugs that treat non-communicable diseases under compulsory licensing.[21]

Identically, there is a knee-jack reaction especially among developing and least developed countries in handling of chronic non-communicable diseases that are equally deadly. For instance, the data obtained from Thailand in 2006 showed that close to thirty thousand patients succumbed to cancer compared to twenty thousand who perished from AIDS-related complications. This data was crucial in the bid for Thailand to apply for compulsory license for Plavix, a drug used for treating heart ailments. Likewise, Natco a generic drug manufacturer based in India in its application for cancer drug Nexavar illustrated that there are more than twenty-four thousand annual deaths resulting from cancer-related complications.[22]

Despite the fact that developing and least developing countries are demonstrating using these fatalities to build a *prima facie* case to obtain compulsory licensing, several hurdles still stand in their way to obtain these vital compulsory licenses. To begin with, the

[20] Paramita Dasgupta, *The WTO at the Crossroads* (Concept Publishing Company, 2009) 97
[21] Andrew Prentice and Chidi Nweneka 'Food and nutrition' in David Mabey, Geoffrey Gill and Martin W. Weber (eds.), *Principles of Medicine in Africa* (Cambridge University Press, 2013) 24
[22] The Economist, 'Cancer in the developing world: Worse than AIDS' (The Economist , Mar 1st 2014) http://www.economist.com/news/international/21597962-burden-cancer-falling-increasingly-heavily-poor-worse-aids accessed 26th March 2017

literal interpretation of the Doha Declaration this only considers communicable diseases and it is loudly silent on non-infections chronic diseases that are equally deadly. Correspondingly, there is inadequate public enlightenment concerning non-communicable diseases among a vast majority of citizens residing in developing and least developed countries. Further, there is a misconception that chronic non-communicable are a preserve of the rich and only afflicts wealthy countries. This position makes it difficult for pharmaceutical manufactures from developed countries to grant compulsory licenses for their generic manufacturing counterparts at an affordable price. Uniquely studies have shown that these chronic non-infectious ailments can be treated through non- pharmaceutical procedures, a position that compounds the already existing challenges of obtaining these medications under compulsory licensing as they are deemed 'non-essential.'[23]

As expected, pharmaceutical manufacturing companies from developed countries are likely to vehemently to oppose any subsequent attempt to broaden the scope of compulsory licensing to encompass chronic non-infectious disease. Remarkably, these pharmaceutical manufacturers maintain that drugs used to treat chronic non-infectious ailments are their main source of revenue. In addition, these pharmaceutical giants cite that decline in revenue will inevitably lead to catastrophic consequences such as cutting back on research and direct investments to other jurisdictions.[24]

f. Ambiguity in definition and scope of applicability

Markedly, there have been competing interpretations of TRIPS precipitated by inadequate concrete parameters that define how compulsory licensing should be conducted as envisioned by the Doha Declaration. Principally, 'Paragraph 6 system' as anticipated by

[23] Sarah Joseph, *Blame it on the WTO: A Human Rights Critique* (Oxford University Press, 2013) 228
[24] Saba Danawala and Zoe Zhang, 'Implications of TRIPS Flexibilities for Access to Non-communicable Disease Medicines in Lower and Middle Income Countries' [2013] 1:1 *GSTF International Journal of Nursing and Healthcare* 1, 3

Doha Declaration only empowers individual countries to determine what constitutes national emergency as a pre-condition for application for a compulsory license. Uniquely, these competing interpretative approaches creates a legal lacuna which provides a fertile ground for instituting litigation on patent infringements.[25]

The flexibility scope of application for compulsory license is often open to misuse and abuse. Pharmaceutical manufacturing companies are often sceptical and quick to resist any attempts to grant compulsory licenses in their belief that some of these applications are marred by *mala fides*. Interestingly, these allegations are not farfetched as the applications of some compulsory licenses have been designed to line the pockets of some corporate entity instead of being a response to dire situations. In Egypt for instance, compulsory license was given for Viagra drug yet erectile dysfunction was neither an emergency nor fatal. Although such situations are few and far between, pharmaceutical manufacturers from developed jurisdiction often cite these scenarios in their bid to resist compulsory licensing as if these occurrences were indeed common.[26]

Identically, the scope of countries that should be considered for compulsory licensing is also a contentious issue. This position also has dire repercussions. For instance, some pharmaceutical manufacturers may decide to deliberately invest in the manufacture of certain medical drugs in a bid to avoid being subjected to compulsory licensing. The potential greatest losers when this happens are developing and least developed countries that are not capable of manufacturing the drugs they need most. By the same token, there is no

[25] Dina Halajian, 'Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem,' [2015] 38:3 *Brooklyn Journal of International Law* 1191,1207-1211
[26] Ibid

universally accepted interpretation of Article 27(2) of TRIPS therefore aggravating the problem of improving accessibility of medical drugs to developing countries.[27]

Furthermore, countries have been known to take advantage of these varying interpretations to interpolate their positions to align them with their self interests. Countries like India which have been on an upward trajectory on matters of pharmaceutical are not only willing to grant compulsory licenses but also export cheap generic drugs to other developing countries. Giant pharmaceutical manufacturing companies are likely to watch India with keen interest as it is classified as a developing country yet it possess pharmaceutical manufacturing capabilities that can match some developed countries. Besides, India is able to use its position as a developing country to import drugs under compulsory licensing. Thereupon, developed countries could construe jurisdictions like India using 'Paragraph 6 system' to gain unfair advantage.[28]

Similarly the vagueness presented due to the narrow interpretation of Article 30 of TRIPS by WTO dispute resolution panel could further aggravate the existing problem of accessibility if drugs for developing countries. Patent holders are often anxious of receiving adequate remuneration from their innovation when it is subjected to compulsory licensing. Moreover, TRIPS is ineptly designed to sufficiently determine the real value of a specific pharmaceutical invention. Likewise, parallel importation interpretation is also shrouded in vagueness. According to 'Paragraph 6 Decision' medical drugs designed for export must be distinctly labelled to forestall diversion. Conversely, an insufficient monitoring system poses the greatest danger to vices like parallel exportation and re-exportation.[29]

[27] Ibid
[28] Ibid
[29] Ibid

g. Retaliations from pharmaceuticals and developed countries

Developing and least developed countries are often timid in deploying compulsory licensing, lest they might face dire economic consequences. Pharmaceutical companies are a direct source of employment and direct investment to developed countries. For example, Abbott threatened to withdraw certain drugs from Thailand if Thailand went forward with its decision to compulsory license HIV drug, Kaletra. Additionally, pharmaceutical manufacturing companies have always cited that compulsory licensing has a long term negative result because it hampers research and development of medical drugs that treat diseases that specifically afflict developing countries.[30]

Developing countries also have to contend with retaliatory actions from developed counterparts. The invoking of 'paragraph 6 system' might be construed as patent infringement and developed countries might impose sanctions. Comparatively, This is the most effective arm-twisting technique as sanctions have the capability of erasing all the merits of granting a compulsory license. After conducting a cost-benefit analysis, most developing countries opt to forego the use of compulsory licensing with the hope that they will recoup certain economic benefits elsewhere. For instance, the United States of America (US) threatened to include Thailand in the United States' Special 301 Watch-List Report where the US imposes sanctions on countries that are notorious for violating intellectual property rights. Faced with this threat, Thailand abandoned its quest to seek a compulsory licence for didanosine, which was an HIV drug. To appease the US, Thailand went further and amended its law to curtail parallel importation and compulsory licensing.[31]

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[30] Charles McManis and Jorge Contreras, 'Compulsory Licensing Of Intellectual Property: A Viable Policy Lever for Promoting Access to Critical Technologies' in Gustavo Ghidini, Rudolph J.R. Peritz and Marco Ricolfi (eds.), *TRIPS and Developing Countries: Towards a New IP World Order?* (Edward Elgar Publishing, 2014) 112

[31] Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (Oxford University Press, 2011) 151

Correspondingly, Developed countries are known to impose stringent measures on developing countries to effect patent protections that are way beyond the requirements of TRIPS. These are made possible through bilateral trade agreements which primarily serve the interest of the developed country. Further, developed countries have a diminished bargaining power and they are likely to ratify unfavourable trade agreements. For instance, the Anti-Counterfeiting Trade Agreement ("ACTA") has vastly faced criticism for hampering the access of pharmaceutical drugs by the developing countries that conclude such agreements.[32]

h. Expected legal difficulties in invoking 'Paragraph 6 System'

Legal challenges are often expected due to the complexity of interpreting compulsory licensing laws. These legal hurdles erode meaningful benefits that are derived from compulsory licensing such as inflation of costs. South African government was sued by US pharmaceutical manufacturers who alleged that South African Medicines and Related Substances Control Amendment Act of 1997 claiming that it was in contravention of TRIPS. Three years later, US brought an action against Brazil for invoking compulsory licensing by relying on Brazilian Industrial Property Law at WTO Dispute Settlement Body. Equally, Bayer Pharmaceuticals commenced legal proceedings against Natco and Cipla who were generic pharmaceutical manufacturers for patent infringement.[33]

i. Conclusion

As it has been illustrated, 'Paragraph 6 System' has not achieved its intended objective by guaranteeing accessibility and affordability of patentable pharmaceutical drugs through the use of compulsory licensing. To begin with, most developing countries are ill-

[32] Dina Halajian, 'Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem,' [2015] 38:3 *Brooklyn Journal of International Law* 1191,1215

[33] *Bayer Corporation v. Natco Pharma Ltd*., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai) explained in Mansi Sood, 'Natco Pharma Ltd. V. Bayer Corporation and the Compulsory Licensing Regime in India,' [2013]6 *NUJS LAW REVIEW* 99

equipped to take advantage of this flexibility. The level of operation sophistication is way complex than what many developing countries can muster. Most governments from developing countries have been blamed for not being sensitive to the needs of its citizens such as prioritizing the acquisition of vital pharmaceutical drugs. Uniquely, 'Paragraph 6 System' is a series of complex legal, administrative and technical complexities in itself. This position explains why many countries have not been able to utilise the process. Moreover, critics have argued that these complexities gobble up much of the resources making it economically unfavourable to use the process.[34]

Even if a country is not resource deficient to use this process, it still has to contend with the fact that its implementation is a logistical nightmare. Its uptake has been limited, and some countries have been guilty of misusing the process to achieve a competing agenda. Besides the Doha Declaration is not expressly clear on chronic non-communicable diseases which are currently more deadly than their infectious counterpart. Inadequate enlightenment and poor perceptions have been blamed for this current state of affairs. Despite the fact that developed countries have tried to build a prima facie case using statistics, they have fallen on deaf ears.[35]

Correspondingly, 'Paragraph 6 System' is terribly ambiguous in many aspects of its operation capacity because it does not set clear benchmarks on how and when it should be applied. Therefore countries are left on a frolic of their own to determine the operation parameters. Moreover, developed jurisdictions have consistently discouraged their developing counterparts from utilising the system. Developing countries have been

[34] Dina Halajian no 32 above, 1202-1220
[35] Ibid

intimidated by retaliatory actions and have opted to appease their counterparts rather than enforce their rights under 'Paragraph 6 System.'[36]

Although the current 'Paragraph 6 System' is a reformed system, more reform is evidently needed to address the issues raised for this system to have any meaningful impact on the accessibility of drugs.

[36] Ibid

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